A tobacco-free society or harm reduction?

Which objective is best for the remaining smokers in Scandinavia?

Karl Erik Lund

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The Norwegian Institute for Alcohol and Drug Research (SIRUS) was established on 1 January 2001 by the amalgamation of the National Institute for Alcohol and Drug Research (SIFA) and the Documentation Section and library of the Norwegian Directorate for the Prevention of Alcohol and Drug Problems. The aim of SIRUS is to carry out research and to disseminate information related to alcohol and drug issues, with a special emphasis on social science issues. The Institute is also the contact organization for the European Monitoring Centre for Drugs and Drug Addiction in Lisbon, EMCDDA.

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Foreword

When I was working on the report of a governmental project to evaluate the public measures that were initiated in Norway during the period 2003-2008 to prevent the use of tobacco (Aarø, Lund, Vedøy, Øverland 2009), one of my tasks was to write a short concluding chapter about future challenges for tobacco policy. To the dismay of my co-authors, this chapter never materialized. Instead, the project ended up as this 85-page report about harm reduction, or more precisely about how harm reduction – the transition to less hazardous nicotine products for smokers who are unable or unwilling to quit – should be an additional element in a *future* disease preventive strategy, particularly in countries in which most of the known measures to prevent smoking are already being utilized.

For many years I was a neutral but fascinated observer of the international debate about harm reduction. Gradually I have taken a conditional supportive stance to harm reduction, but as a supplement to the traditional measures to prevent the use of tobacco. Even though harm-reduction ideology has great support in relation to other types of risk behaviour, such as the use of drugs, most authoritative health bodies in Scandinavia are still sceptical to its use in the area of tobacco. However, as the debate has developed, resistance has become weaker, and in Norway, the health authorities have recently allowed health care personnel in individual cases to advise inveterate smokers to use low-nitrosamine smokeless tobacco (Swedish snus).

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Summary

Harm reduction means that cigarette smokers who are either unable or unwilling to stop using nicotine products are encouraged to switch to nicotine products with much lower health risk.

Harm reduction has previously been debated in various forms in the area of tobacco when filter cigarettes were introduced in the 1960s, and when so-called "light cigarettes" with reduced tar and carbon monoxide content were introduced in the 1980s. However, epidemiological research has shown that the health benefits associated with switching to such products have been small – perhaps even non-existent. The result of such previous negative experience is that the health authorities in most countries have shown very little enthusiasm for new preventive strategies that include switching to tobacco and nicotine products that are less damaging.

However, the current debate about harm reduction is different from the previous debates in that this time real risk-reducing products (snus, medicinal nicotine products and other non-medicinal nicotine products) are being discussed. There is consensus that a switch from cigarettes to such products would involve a significant reduction in risk for individual smokers. The reason for current scepticism is primarily uncertainty about what a harm reduction strategy could lead to at the population level. In addition, the established measures that the authorities in Scandinavia have introduced to reduce smoking have been very effective, and why not just intensify their use? If snus were added to the arsenal of harm-reducing products, for example, this would go against the stated aim of the authorities to achieve a totally tobacco-free society.

Some of the important areas that are discussed in this report:

- Despite the fact that measures to prevent smoking have been effective, and the proportion of smokers is decreasing in Scandinavia, the need for harm reduction measures has become greater because:
    - There is an imbalance between the motive to stop smoking that the authorities have created with campaigns, duties, restrictions etc, and the help that is offered to people who are trying to stop smoking. Nicotine replacement products are used to a small extent. The amount of assistance provided by health care personnel is moderate. In addition,

the effect of nicotine replacement products and the effect of interventions provided by doctors is very limited.
    - The remaining group of smokers increasingly contains a higher proportion of people with social, mental and demographic characteristics associated with reduced ability to stop smoking.
    - For twenty years there has been a social gradient in smoking pattern in Scandinavia. The search for measures that are tailor-made for smokers with specific characteristics, for example short education, has been going on for a long time. Literature reviews have not identified measures that the authorities could implement in order make the social gradient in smoking pattern less steep.
    - In Scandinavia, nearly all the political measures recommended by WHO for reducing smoking have already been implemented. There is probably little potential for further reduction by using publically-regulated control of tobacco. Despite the fact that tobacco control measures are utilized to such a degree, the proportion of deaths due to smoking among adults is still very high.
    - Intensifying the existing measures against smoking that have been effective up to now would probably give only a moderate return (diminishing marginal returns).
    - Cigarette smoking is ideal for a harm reduction strategy, because the substance that causes addiction – nicotine – is not the cause of the health risk. People smoke because of nicotine, but die from tobacco smoke. Much less hazardous nicotine products are available.

- Harm reduction is an obvious strategy for a many other areas of risk. The reason why the debate about harm reduction in the area of tobacco has come later, is probably related to the widespread belief that it is possible to achieve a tobacco-free society.

- If the authorities in the Scandinavian countries wish to even out future social differences in health in the population, a harm reduction strategy in the field of tobacco may be appropriate.

- In order for harm reduction to be successful, consumers must receive correct information about the relative health risks of

different types of nicotine products. Today, both smokers and general practitioners are misinformed.

- The ban that exists in several Scandinavian countries against "new types of tobacco and nicotine products" can function today as a barrier to effective harm reduction in the remaining segment of smokers, and should be replaced with regulations that control "new" nicotine products.

- Production of nicotine products that have higher potential for use than currently available medicinal nicotine products, and that is more effective in stopping smoking, should be stimulated.

- Harm reduction policy must be made legitimate by the authorities. It is clearly a disadvantage and a hindrance for harm reduction if the snus industry is the most visible proponents of harm reduction.

Snus as a harm-reducing alternative:

- The health authorities in Norway and Sweden – where sale of snus is allowed – provide information about the health risks associated with the use of snus, but do not inform smokers about the health benefits that can be achieved by switching from cigarettes to snus. At worst, this can mean that nicotine-addicts remain smokers with no motive to try a harm-reducing alternative.

- The cigarette industry are in the process of buying themselves into the snus industry, and wish to sell snus in addition to – and not instead of – cigarettes. They regard snus as a so-called "bridging product" that can be used in social arenas where there are smoking restrictions in order to keep smokers dependent on nicotine (nicotine maintenance policy). In addition, there are several examples from Scandinavia that the snus industry are carrying out innovative product development with a view to recruiting young people of both sexes.

- Reviews of the scientific literature show that snus is substantially less hazardous than cigarettes. The magnitude of the overall reduction in hazard has been estimated to at least 90%.

- Much research remains to be done before we know the precise effects of snus from a public health perspective. Several issues are not possible to research, but the pattern of use of snus in Sweden and Norway suggests that availability of snus must have a positive net effect on public health. This can be an argument for withdrawing the ban on snus in the EU, but it can also be argued that the pattern of use observed in Scandinavia not necessarily will occur in other countries.

- There is little empirical data from Scandinavia to support the hypothesis that snus increases the risk of starting to smoke. There is some empirical data to support the hypothesis that snus reduces the risk of starting to smoke.

- There are no randomized controlled studies in which the effect of snus on smoking cessation has been measured. Observational data from Scandinavia are consistent in demonstrating that snus leads to an increase in the quit rate for smoking. Self-reports from Norwegian quitters indicates that the effect is greater than the effect of nicotine replacement products.

- An argument for including snus in the arsenal of harm-reducing products is that it has great potential for use in marginalized smoking populations, which include people who have high immunity for traditional preventive measures for smoking.

The structure of the report

The report starts with a discussion of what should be the overall aim of future tobacco policy in countries with an advanced tobacco epidemic: a tobacco-free society or reduction in tobacco-related diseases? Does striving towards a tobacco-free society hinder harm-reducing measures that could save lives?

In the report, the harm reduction debate is presented. The difficult climate for discussion, resulting from harm reduction being an ethical issue, is discussed. In a society where tobacco has become "our worst enemy", that everyone can be united in fighting against, it is easy to regard harm reduction as an untimely course of action, and to dismiss it by labelling it as tobacco liberalism.

I then show how harm reduction will become increasingly relevant and appropriate in Scandinavia, among other things because political measures can have attained their full effect, while levels of harm remain high. Harm reduction may also become appropriate because the group of remaining smokers in Scandinavia will consist of more and more people with the psycho-social characteristics of people who are difficult to influence just by more intensive use of the traditional preventive measures against tobacco. I argue that harm reduction will be an appropriate measure for achieving the aim of the authorities to reduce inequalities in health between different social groups.

Harm reduction may also become appropriate because there is an imbalance between the strong desire for smokers to stop smoking that the authorities have created (with campaigns, restrictions and duties), and the moderate supply and mediocre effect of the help that is offered to people who are trying to stop smoking. We also discuss how biased information about the relative health risks associated with the use of different tobacco products has created misinformed consumers who are unable to make optimal choices.

1 A tobacco-free society or harm reduction?

The aim of this report is to stimulate a debate about whether *harm reduction* should be included in the arsenal of preventive measures for smoking. If this was the case, harm reduction ideology would challenge the traditional paradigm for control of tobacco, which briefly involves eliminating all use of tobacco. In the light of the psycho-social and demographic characteristics of today's smokers, we shall pose the question of whether a tobacco-free society is a realistic and sensible aim in the short term. Is elimination of all use of tobacco – "the null vision" – particularly appropriate if the real aim is to prevent tobacco-related illness and death in the remaining group of daily smokers? Has *the best solution* (a tobacco-free society) become *our worst enemy* (reduction in tobacco-related mortality)? Instead, should the authorities accept harm reduction, such as, for example, in the area of drugs.

1.1 Definition of harm reduction

In a report published in 2008, the American Association of Public Health Physicians dealt with the application of the principle of harm reduction in the field of tobacco, and proposed the following definition of harm reduction:

> *"Harm reduction is taken to mean encouraging and enabling smokers to reduce their risk of tobacco-related illness and death by switching to less hazardous tobacco products. This switch could be short-term or long-term, partial or full, with the understanding that every time an alternative tobacco product is used in place of a cigarette, risk of tobacco-related illness and death is reduced"* (AAPHP 2008: 2).

The Institute of Medicine in the USA dealt with harm reduction in the book *"Clearing the Smoke. Assessing the Science Base for Tobacco Harm Reduction"* from 2001, and defined the concept in the following way:

> *"A product is harm-reducing if it lowers total tobacco-related mortality and morbidity even though use of that product may involve continued exposure to tobacco-related toxicants"* (IM 2001: 2).

To an increasing degree, tobacco research has been concerned with the effects that harm reduction could have. In the article *"Charting the Science of*

the Future. Where Tobacco-Control Research Must Go", the eminent American researcher Kenneth Warner maintains that the harm reduction debate is the most important thing that has happened during his 30 years as a tobacco researcher (Warner 2007). But before harm reduction can be included as a strategy, there are several issues that must be clarified:

> *"Should products less hazardous than cigarettes, including tobacco products, be promoted as alternatives to smoking for smokers who are unable, or unwilling, to quit? If, so, is it possible to target promotion so finely, thereby avoiding encouraging others to use a product, still risky, when otherwise they would have abstained entirely? What kinds of products should be considered as acceptable members of the tobacco harm reduction arsenal? For example, is it advisable to promote low-nitrosamine smokeless tobacco products (snus) as much less hazardous than cigarettes (which they certainly are)? How can the population impact that will follow from the introduction and promotion of ostensibly less hazardous products be assessed? What surveillance system could evaluate use patterns, and ultimately health consequences, when confronted with possibly a dozen or more qualitatively different types of products and the hundreds of mixed use patterns that would emerge? Indeed, short of waiting 30 years for the (possibly inadequate) epidemiological evidence, how can risk reduction potential be evaluated scientifically?*
>
> *The questions are endless, with none of them leading to easy resolution. Yet, "Harm Reduction" may be an important wave of the future. Will it join prevention, cessation and protection of others as the fourth pillar of comprehensive tobacco control?"* (Warner 2007: 315-6).

1.2 What does harm reduction involve for the area of tobacco?

In Scandinavia, the harm reduction debate began for the area of tobacco after having its counterpart in a series of other areas of risk behaviour, including drug use (handing out syringes, premises for injection of drugs, methadone projects, heroin prescribed by doctors), use of alcohol (blood alcohol limits, point abstinence, temperance) and gambling (less aggressive gambling machines). That the area of tobacco has not been a topic for harm reduction until recently, indicates how deep-rooted the vision of a tobacco-free society is. In addition, the reduction in smoking in Scandinavia during the last decade has given many people the impression – realistic or otherwise – that use of tobacco can actually be eliminated. According to some, to debate harm reduction in the area of tobacco has

turned out to be more provocative and challenging than in other areas (Sweanor 2007).

Many people also believe that harm reduction in the areas of drugs and tobacco, for example, are so different that we are talking about two different phenomena. However, it is interesting to note that several of the traditional arguments used against harm reduction in the area of drugs, can now also be used in the area of tobacco (Table 1).

Table 1. Arguments against harm reduction that can be used in the areas of drugs and tobacco

Drugs	**Tobacco**
Harm reduction implies that public authorities abandon the ideal of a drug-free society	Harm reduction implies that public authorities abandon the ideal of a tobacco-free society
Harm reduction measures such as premises for the injection of drugs are in conflict with the UN conventions that the Scandinavian countries have ratified, and can weaken the countries' credibility in international drug policy issues	Harm reduction measures such as use of snus are in conflict with the recommendations of WHO, and can weaken the Scandinavian countries' credibility in international tobacco policy issues
Premises for the injection of drugs and the handing out of free syringes can maintain and reinforce injection culture – the most hazardous type of heroin use in relation to overdoses	Smokers who are advised to switch to snus will maintain and perhaps increase their addiction to nicotine, which can increase the probability for starting to smoke again – the most hazardous type of nicotine use
Harm reduction in the field of drugs can weaken drug users' motivation for treatment and rehabilitation	The introduction of less harmful alternatives to smoking will mean that smokers who otherwise could have completely stopped using nicotine now continue to use a nicotine product with uncertain consequences for health
It is difficult to regard the existence of an offer that makes it possible to continue to use drugs as an incentive to stop using drugs.	It is difficult to regard the existence of an offer that makes it possible to continue to use nicotine as an incentive to stop using nicotine.

1.3 Informed consumers

Another implication of harm reduction ideology is that consumers should be able to choose to move downwards on a risk continuum, by being offered precise information about alternative nicotine products. This is far from present-day reality in e.g. Norway, where studies show that consumers have serious misconceptions about relative health risks (Øverland et al 2008). This also applies to Norwegian general practitioners in a study conducted in 2008 (Lund et. al to be published). For example, the health hazards of both snus and medicinal nicotine products compared to smoking are exaggerated. If these misconceptions are not corrected, the result may be that smokers loose a motive for choosing a less hazardous nicotine product. In several reports, the American nicotine researcher Lynn Kozlowski has claimed that correct information about the relative health hazards of different nicotine products must be regarded as a human right.

> *"Cigarettes kill about half of those who smoke them. It is urgent to inform smokers about options they have to reduce risk. Public health policy in this instance lacks compelling justification to override the human rights of the individual"* (Kozlowski 2002).

> *"Public health concerns should trump individual rights only when there is clear and convincing evidence of harm to society. Lacking that evidence, individual rights should prevail"* (Kozlowski 2003).

The situation with uninformed smokers (and doctors) can be the result of unfortunate but unintended biased information from the health authorities. In Canada, the researchers Carl Phillips et al. (2006) – though they do have close connections to the snus industry – have accused North American health bodies for having tacitly accepted the situation because their hatred of tobacco has prevented correct information about snus being given out.

> *"Certain health advocates believe it is acceptable to mislead people into making choices they would not otherwise make...Through the use of various tactics, advocates who oppose the use of Smokeless Tobacco as a harm reduction tool have managed to convince most people that the health risk from Smokeless Tobacco is several orders of magnitude greater than it really is. The primary tactic they use is making false or misleading scientific claims that suggest that all tobacco use is the same…Apparently motivated by their hatred of all things tobacco, they are trying to convince people to not switch*

> *from an extremely unhealthy behavior to an alternative behavior that eliminates almost all of their risk"* (Phillips et al 2006: 19).

In its information, health authorities typically highlight the following: 1. snus is carcinogenic (pancreas and oesophagus), 2. other diseases cannot be discounted (cardiovascular diseases, diabetes, obesity, impotence, preeclampsia), 3. snus leads to dependency, and 4. snus should not be used when giving up smoking. The Norwegian Directorate of Health e.g. says little about the great difference in relative risk between snus and cigarettes. Is the information given adequate for consumers to be able to make an informed choice? In the article "*Not safe is not enough: smokers have a right to know more than there is no safe tobacco product"*, Kozlowski & Edwards (2005) addressed the issue of information in connection with harm reduction. Their criticism may also be relevant for the situation in Scandinavia.

> *"The 'not safe' or 'not harmless' messages don't address the reality that some tobacco products are substantially safer than others... Saying tobacco 'isn't safe' isn't incorrect, but it isn't saying enough. Going beyond the no safe tobacco message to provide better information on the nature of risks from tobacco products and nicotine delivery systems is necessary to respect individual rights to health relevant information."*

1.4 The climate for the harm reduction debate

In Scandinavia, the debate about harm reduction in the area of tobacco has had a difficult start. Up until now, neither those who have been involved in measures to prevent tobacco-related harm, nor those involved in developing tobacco policy, have invited people to deal with the principle of harm reduction in a systematic way, such as is the case, for example, in the area of drug use. The Norwegian Minister of Health has in 2008 in fact invited people to a debate about prescription of heroin by doctors.

The result of this is that harm reduction policy has not been taken up by those who have an influence in this area. To the extent that exchange of views has taken place, this has typically been initiated by the media, with subsequent exaggerated polemic coverage of for-and-against arguments. This has been disadvantageous for the debate. In addition, the five Nordic ministers of health prepared a document that effectively terminated all expectations that steering bodies could initiate a debate about harm

reduction in the area of tobacco (Holm et al. 2008). Among researchers, who work systematically with testing the strength of for-and-against arguments, this type of "dogmatic bulletin" creates a certain degree of astonishment.

Articles in international scientific journals such as The Lancet, Addiction, Nicotine & Tobacco Research, Journal of Harm Reduction and Tobacco Control have contributed significant knowledge in this area. But also here, the discourse is characterized by a polarized disagreement that has rarely occurred in the tobacco research literature.

The people involved in the debate about harm reduction can be divided roughly into five general types, according to, for example, their debating style. The groups in the table are, of course, neither all-embracing nor mutually exclusive, but they provide the reader with a general overview. However, it is difficult to place the purists who, for opportunistic reasons, disguise their hatred of tobacco by using the scientific arguments of the sceptics, or the people from the industry who try to increase their credibility by camouflaging their profit motive with the scientific arguments of the pragmatists.

Table 2. Typology of people involved in the harm reduction debate in the area of tobacco

General type	Main argument	Debating style
Purists	All tobacco is dangerous and must be eliminated. To grade the health risks of different products is a dead end	Accusing people of having ulterior motives Criticism of researchers Emotional (and rational) hatred of tobacco Moralistic orientation to duty ethics Puritanism Agitation disguised as science
Sceptics	Harm-reducing products delay the elimination of tobacco use and can result in a negative net effect at the population level. Alright at the individual level	The precautionary principle Demand empirical data Scientifically orientated
Pragmatists	The characteristics of today's smokers make harm reduction timely. Working towards a tobacco-free society hampers the transition to less hazardous nicotine products that can save life	Experience from treatment Empiricists Scientifically orientated Knowledge base in favour of harm reduction
Proponents	Harm reduction has only positive aspects	Dedicated Agitation disguised as science
The snus industry	Our products are the solution to the tobacco problem	Selective information People paid to provide information / to carry out research

In order to illustrate the differences of opinion between the purists/sceptics (PS) on the one side and the pragmatists/proponents (PP) on the other side, we can allow them to take their positions in a hypothetical debate. In this debate, the PSs stress that use of snus increases the risk of cancer of the pancreas. The PPs point out that the risk of cancer of the pancreas is almost halved if cigarettes are replaced with snus. The PSs then point out that the *increase* in risk will apply to new users of snus who have no previous experience of smoking, and if we get enough new users, the effect at the population level will be negative. The PPs reply that, in total, the health risk of snus is at least 90 per cent lower

than with smoking, so that there must be 90 per cent more users of snus than smokers in society in order for the net effect to be negative – and such an increase would be completely unrealistic. The PPs also point out that the pattern of use of snus shows that most users have previously been smokers – there are actually few people who begin directly with snus. The PSs reply that this will not necessarily be the case for very young people. Snus is often the first product they use. The PSs will also not exclude the possibility that young people who start to use snus are vulnerable for starting to smoke (the gateway hypothesis). The PPs take a completely different standpoint, and mean that snus probably functions as a protection against young people starting to smoke – if snus were not available, these young people would otherwise have begun to smoke (the immunization hypothesis).

2 All the measures are being fully utilized – but many people are still dying

The public measures that are used in Scandinavia to prevent use of tobacco, as in other countries, have been focussed on three areas:

i) to prevent young people from beginning to smoke *(prevention)*
ii) to motivate and to help people who are established smokers to stop smoking *(cessation)*
iii) to protect third parties from involuntary exposure to passive smoking *(protection)*

This has been an extremely successful policy. It is satisfying to confirm that Scandinavian tobacco policy has provided a model example for other countries and for international recommendations, such as WHOs Framework Convention on Tobacco Control (FCTC). Within Scandinavia, Finland and Norway in particular have set the trend. Norway has had comprehensive tobacco legislation, which, among other things, from 1975 led to a total ban on all tobacco advertising, introduced health warnings on tobacco packets and sat the age limit for buying and selling tobacco at 16 years. Further provisions were added to the legislation to protect people from passive smoking in the workplace and on public transport (1989) and places where food and drinks are served (2004), to forbid new nicotine products (1989), to introduce more (1984) and larger (2003) health warnings, and to increase the age limit to 18 years (1995). The ban against visible display of tobacco products in outlets, and colour illustrations of damage to health on packets, will be introduced in 2010. At the same time, the real price of tobacco has increased, systematic anti-addiction measures have been introduced with, for example, the establishment of the free telephone service Quit-line, general practitioners now receive a fee for counselling on stopping smoking, and campaigns have been intensified. The efforts of the authorities have contributed to speeding up the reduction in the number of smokers, but the reduction is also the result of other factors outside the direct control of the authorities, such as the change in the symbolic aspect of smoking (Scheffels 2008, Lund 2008) and the fall in social class of the group of people who smoke, which has reduced their importance as agents for promoting smoking (Lund & Lund 2005).

One of the results of Norwegian tobacco policy has been that the proportion of smokers who are men has almost halved since the 1960s and the increase in the number of women smokers has stopped at a much lower level than the top level for men. In 1973, there were more than twice as many smokers as former smokers in the population, but this ratio was 1:1 in 2009. The reduction in the proportion of smokers and the fall in the use of tobacco have occurred in parallel with a change in attitude to tobacco in a negative direction, and an increase in knowledge about the adverse health effects of tobacco (Lund 1996). Preventive work in the field of tobacco in Norway has been used to illustrate how effective state intervention against risk behaviour can be (Elvbakken & Stenvoll 2008).

Because Norway – along with the other Nordic countries - has already introduced more or less all the elements in the internationally recommended package of measures against tobacco, it looks as though we have come as far as it is possible to come with the measures that we know about today. NGO's with support from central professional organizations have always managed to create legitimacy for introducing new measures, and politicians and public officials have worked to implement them. The questions that are asked more and more often in countries with a history of similar tobacco control policy as the Scandinavian countries are "*What do we do when the measures have attained their full effect? What is left when politicians have already used all the tools in their tool box? Is the solution to intensify use of the existing measures?*"

2.1 Intensified use of existing measures?

Because Scandinavian tobacco control policy has been successful, it can be tempting and quite easy to use more intensively the measures that have been shown to be effective. But there are practical and political problems with this. Also, it must be expected that intensified use of these measures will lead to diminishing marginal returns. Let us explain in more detail why we should have limited expectations about the effect of intensified use of the old measures.

2.1.1 Duties and taxes

In the present-day situation, where border trade and import of tobacco from abroad amounts to almost 40 per cent of total sales in Norway (Melberg 2007), it would probably be almost politically impossible to introduced anything other than inflation-adjusted changes on duties. A

more realistic aim would be to maintain the level of duty at the present level (Lund 2005, Melberg 2007).

2.1.2 Restrictions on places where smoking is allowed

Further restrictions on places where smoking is allowed would also probably give little further benefit, because smoking is already regulated in so many of our most frequented places (work-places, public transport, public squares, places where food and drinks are served etc.). The medical justification for introducing smoke-free outdoor places (primarily parks, beaches, lay-bys, places where food and drinks are served outside, parking places, sports arenas, golf courses) is much weaker than the justification for restricting smoking indoors, because the concentration of tobacco smoke seldom reaches hazardous levels (with the exception of for groups of people who are especially vulnerable). It is fairly improbable that reasons such as minor discomfort, litter, unpleasant smell and the sight of people smoking can justify legislative control of smoking outside, even though some researchers have argued in favour of this (Repace 2008). Even if this type of restriction was introduced, it would probably have only a marginal effect on the normative pressure against freedom to smoke that already exists in places where people gather.

Legislative regulation of smoking in *private places*, such as in the home and in cars could be considered because of regard for children, who are particularly vulnerable to exposure to tobacco. This could have an effect on adults' smoking behaviour in places where children are present. However, studies have shown that most families already have rules to reduce smoking in the home and in cars to a minimum (Helgason & Lund 2001), and that smoking in the vicinity of children is already declining rapidly without such regulation (Lund et al. 2004).

Excluding smokers from being employees has, for example, been practised by the World Health Organisation (WHO) since 2005. This measure led both to general protests and to a heated debate in traditionally tobacco-hostile communities, such as GlobaLink (a web site for researchers, bureaucrats and activists in tobacco control). In the article "*Going too far? Exploring the limits of smoking regulations",* Simon Chapman, Australian professor in public health and former editor of the scientific journal "Tobacco Control", claimed that supporters of the ban practised bizarre, paternalistic and unscientific arguments for null tolerance (Chapman 2008). This practice might result in social apartheid policy. No

serious agents in the health field has so far recommended such rules in Scandinavia, and this will probably not happen in the near future

On the other hand, several employers have introduced a ban on smoking in working time for their employees. Some of the first organizations to do so were voluntary organizations such as Cancer Societies and Heart and Lung Associations, and some hospitals. Several municipalities have also introduced, or will introduce, such regulations for their employees. The justification is protection of both individual smokers and people around them. The profile of the workplace and economic considerations have also been used as arguments. Authorities are also planning to introduce an all-day total smoking-ban throughout working hours for both students and teachers in all schools including upper secondary schools. The idea of providing role models is one of the justifications. Research shows that smoke-free working time reduces the prevalence and the intensity of smoking among employees and pupils (Fichtenberg et al 2002, Levy et al 2003), so here there is potential for further reduction in smoking.

2.1.3 Restrictions on sale of tobacco

To raise the age limit for buying and selling tobacco above the age of consent of 18 years of age – if at all politically possible – would probably have modest effect. Today, all people under 23 years of age are required, unsolicited, to confirm their identification when they buy cigarettes. Raising the age limit, for example to 19 years of age, would probably have some but little effect on recruitment. However, studies have shown that many under-age smokers buy their own cigarettes. Improving the enforcement of the present age-limit regulations, for example by introducing licences and threatening licensees with losing their licence if they sell tobacco to under-age persons, would perhaps be more appropriate.

Reducing the number of places that sell tobacco and shortening the hours for sale of tobacco, could be another measure. Today tobacco can be bought 24 hours a day in the whole of Scandinavia. However, reduced availability has not been discussed in Norway since the idea of a state monopoly of tobacco sales outlet was rejected at the end of the 1920s (Lund 1996). This measure seemed to lie far from the political agenda, until the Norwegian Medical Association, in January 2009, recommended restricting sale of tobacco to alcohol sales outlets. This would prevent sale of tobacco from, for example, petrol stations, snack bars and convenience stores.

2.1.4 Restrictions on marketing

All types of direct and indirect advertising, including sponsoring, have been banned for a long time in most Scandinavian countries. Since the legislation is already effective, there is little potential for further restrictions. However, research has shown that there can be benefits from measures such as making health warnings on packets visible (Hammond et al. 2007), plain packaging of tobacco products (Freeman et al. 2008) and a ban on visible display of tobacco products (Lund & Rise 2008).

2.1.5 Information

Scandinavian health authorities have conducted many different campaigns to change attitudes and to provide information. Launching new campaigns would be very costly, and would require more funding than the health authorities have at their disposal. New anti-smoking campaigns would possibly be taken notice of by a new segment of the population who have not been exposed to campaigns earlier – primarily children and young people who have "come of smoking age" since the last campaign. New campaigns would probably also reinforce smokers' motives for quitting, which most smokers already have, and could help to maintain the negative climate to tobacco in society that already exists. 90 per cent of the Norwegian population were after several years able to recall a specific anti-smoking campaign run by the Norwegian Directorate of Health (Larsen et al. 2006, Lund & Rise 2004). Therefore, we should not have high expectations that new campaigns would lead to a big increase in the level of information in the population.

2.1.6 A fee for doctors for helping patients to stop smoking

The doctor's fee in Norway is currently (in 2009) 25 Euros. This fee can be claimed twice for the same patient during one calendar year from the first consultation for individual, structured weaning from smoking, as a stage in treatment for disease, according to an approved programme. Some people would claim that the fee does not cover the actual time needed to follow up closely and adequately an attempt to stop smoking, and that this hampers intervention. The effect of assistance from health care personnel to quit smoking is discussed in Section 7.2.

2.2 A comprehensive policy, but many people are still dying

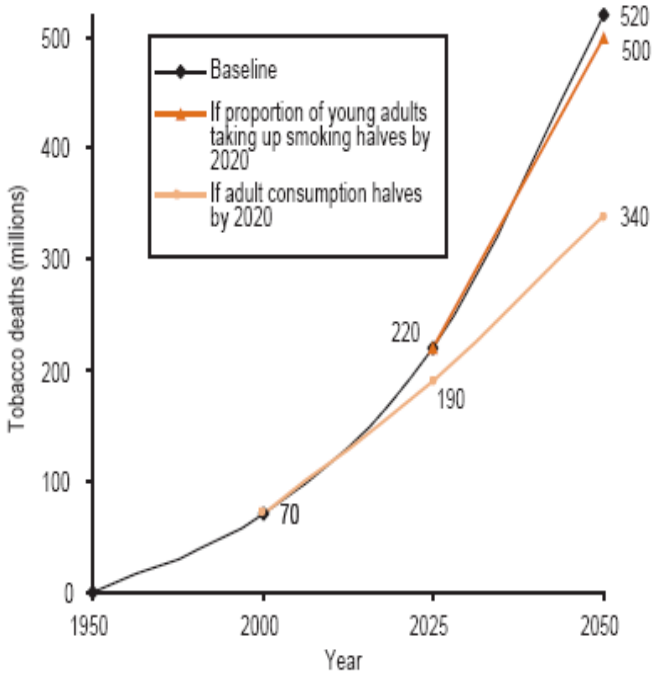
The tobacco policies of the Scandinavian countries have scored high on a European ranking scale from 2006 (Joossens and Raw 2006). With a so robust infrastructure for tobacco control, the potential for improvement is somewhat limited. It is disturbing that the questions about the limitations and inadequacies of tobacco policy are being raised in a situation in which smoking – despite the reduction in use of tobacco – is still one of the absolutely most important preventable causes of disease and premature death in Scandinavia. "*The glass remains half empty",* claims Ken Warner, describing the parallel situation in the US (Warner 2007). According to the Norwegian Institute of Public Health, 16 per cent of all deaths are attributable to smoking in Norway (Vollset et al 2006). The number of tobacco-related deaths in Norway is actually greater today than it was in 1964 when the US Surgeon General published his report on smoking and health. This is because of three factors: i) the population has increased, ii) there is a long time lag between smoking behaviour and the resulting diseases, so that the epidemic of diseases in the 1960s reflected the relatively low, but increasing use of tobacco 30-40 years previously, iii) the health benefits of more recent preventive measures have not yet been reaped, because of the time lag.

3 From a long-sighted to a short-sighted gain timescale in tobacco policy

The delay between the behavioural component and the disease component (the time lag) in the tobacco epidemic means that measures to prevent recruitment to smoking among young people operate with a long-term gain timescale. Perhaps the authorities in Scandinavia would achieve more by being more short-sighted when considering preventive measures. A simulation model launched by the World Bank can be interpreted in this direction. The World Bank compared the health effect of halving recruitment to smoking among young people with the effect of halving adults' consumption. The result is shown in the figure below, from the publication *Curbing the Epidemic* (World Bank 1999).

FIGURE 7.1 UNLESS CURRENT SMOKERS QUIT, TOBACCO DEATHS WILL RISE DRAMATICALLY IN THE NEXT 50 YEARS

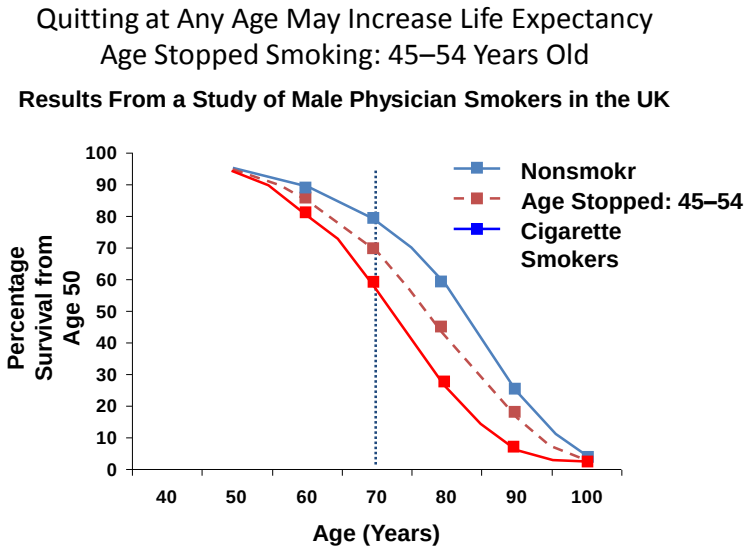
Estimated cumulative tobacco deaths 1950–2050 with different intervention strategies



At the world level, if we succeeded in halving recruitment to smoking among young people from 2000 to 2020, the accumulated reduction in

tobacco-related deaths in 2050 would be 20 million. If we succeeded in halving tobacco consumption among adults (mainly by getting adults to quit smoking), the accumulated reduction would be 180 million deaths. The basis for the estimates of the World Bank were Doll & Peto's (1995, 2004) estimates of survival after quitting smoking at different times in life (see the figure below).

Thus, with a short-sighted timescale, the gain from a reduction in recruitment is relatively modest, while a doubling of the rate of quitting would have an enormous effect. If we are to reduce tobacco-related mortality and morbidity in our lifetime, it is more important to stimulate quitting cigarettes than to prevent recruitment among young people. Harm reduction for today's smokers must also be assessed according to this perspective.

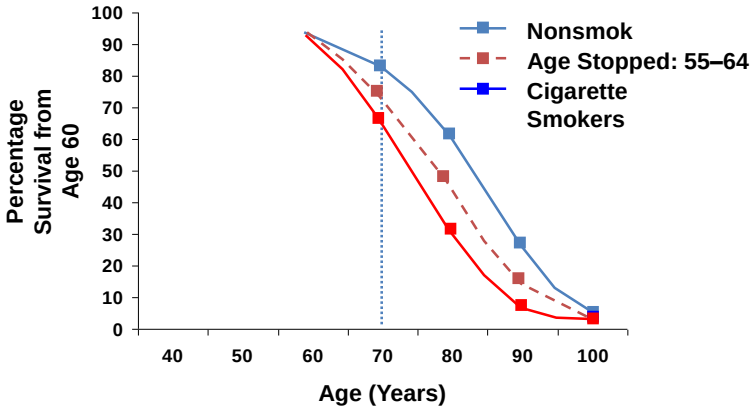


Even quitting smoking later in life can lead to longer life expectancy

1. Doll R, et al. *BMJ*. 2004;328:1519-1527.

Quitting at Any Age May Increase Life Expectancy
Age Stopped Smoking: 55–64 Years Old

Results From a Study of Male Physician Smokers in the UK



Even quitting smoking later in life can lead to longer life expectancy

1. Doll R, et al. *BMJ*. 2004;328:1519-1527.

4 Nicotine products and the legislation

Researchers in the field of tobacco smoking and nicotine consumption now have more complete insight into the toxicology, neuropsychology and physiology of smoking, than they had some decades ago. An important scientific discovery was that the substance in tobacco that causes dependency – nicotine – in its pure form has very few health consequences (somewhat dependent on the level of exposure - the fatal dose is around 60 mg). It is said that *one smokes for the nicotine, but dies from the cigarette smoke*. This means that today's Scandinavian smokers mainly continue to smoke because of their addiction to nicotine, while statistically, the half of them who will end up a fatal smoking-related disease, will do so as a result of the *method of intake of nicotine*.

Research has shown that intake of nicotine by breathing in tobacco smoke from a glowing cigarette *(combustible nicotine delivery device)* is by far the most hazardous method of nicotine intake, and that there are alternative ways of intake that involve a much lower risk to health. There are other, but still not clearly identified, substances other than nicotine that increase the health risks of smoking. For example, it has been shown that when tobacco burns at a high temperature, for example in a glowing cigarette, many poisonous substances are released that can cause cancer and other diseases (IM 2001).

Based on knowledge about the effects of nicotine, a (presently) small selection of alternative products to cigarettes have been developed, that may lead to:

i) uptake of purer nicotine (meaning, purified to remove many toxic substances), or:
ii) blocking/replacing the neuropsychological effects on the brain.

The Institute of Medicine in the USA has called these products: "*potential reduced-exposure products"*, with the acronym PREPs (IM 2001). The table below gives a list (not complete) of cigarette replacement products, both with and without nicotine, that are believed to have a lower health risk than cigarettes.

Table 3. Potential Reduced-Exposure Products (PREPs)

Category	Characteristics	Example
Modified tobacco	Reduced content of certain toxic substances (excluding TSN)	Snus Chewing tobacco
Products that resemble cigarettes	Reduced temperature of burning or heating up	Electric cigarette with battery Premier, Eclipse, Accord (USA)
Pharmaceutical products	Nicotine replacement	Nicotine chewing gum (Nicorette) Nicotine patch Nicotine inhaler Nicotine nasal spray Nicotine pastilles (Zonnic) Nicotine mouth spray (Niconovum) Sublingual tablets with nicotine
	Anti-depressants that reduce nicotine craving	Bupropion (Zyban) Nortriptyline
	Partial nicotine receptor agonists that reduce the feeling of pleasure and reduce nicotine craving	Varenicline (Champix)
Non-pharmaceutical products	Nicotine replacement	Nicotine water Alcoholic drinks with nicotine Nicotine jelly/cream Lollipops/sweets/nicotine wafers/nicotine pastilles

More detailed descriptions of different types of PREPs can be found in a series of publications (RCP 2007, IM 2001. See also the fact sheet published by the American organization TobaccoFree Kids http://www.tobaccofreekids.org/research/factsheets/pdf/0248.pdf). It is a paradox that nicotine products are released on the market without restrictions other than age-limits and a ban on advertising, while the much less dangerous medicinal nicotine products are very strictly controlled. In addition, nicotine articles (for example the electric cigarette) are produced by suppliers that have no connection to the tobacco industry or the pharmaceutical industry. Provisionally, they can be sold freely, without regulations for systematic testing of the effects or the side-effects. One exception is Norway where a total ban on new nicotine products was

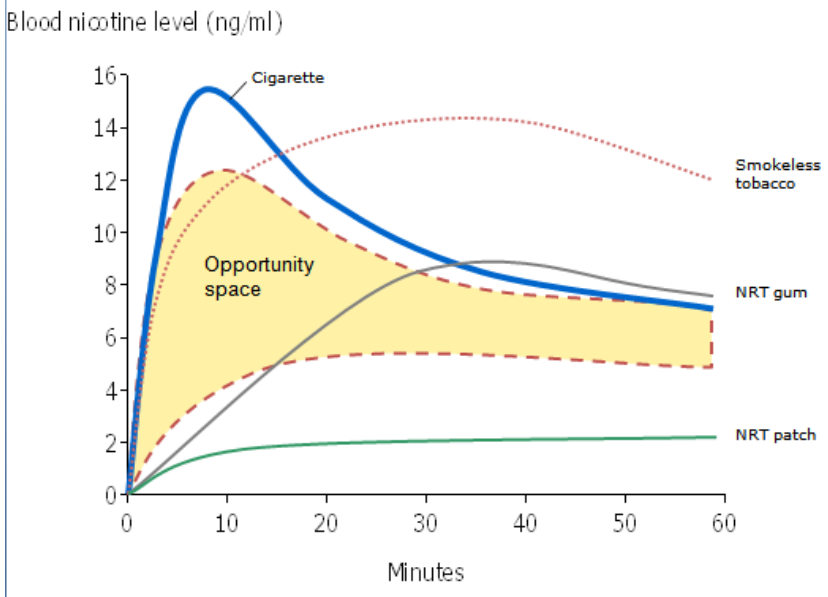
introduced in 1989. The EU introduced a ban on the sale of snus in 1992 (Sweden was granted exemption from this ban when it joined the EU in 1995).

With regard to health, there is general agreement that the existing regulation of the market for the present selection of nicotine products (including snus), paradoxically favours the most damaging of them all – cigarettes. Therefore, in several countries, such as England, the USA, Canada and the EU countries, the legislation that regulates nicotine products is being strongly debated (Gilmore et al. 2008, RCP 2007: 181-9, SCENIHR 2008, Sweanor et al. 2007, Bates et al. 2003, Fagerström & Schildt 2003, ERS 2005).

Both the tobacco industry, the pharmaceutical industry and a diffuse group of other mercantile concerns have been looking for a product that can deliver nicotine in a purer form than cigarettes, but which at the same time offers a similar speed of uptake of nicotine in the blood. Medicinal nicotine products are designed to give such a low dose of nicotine that they will not lead to addiction. The risk of addiction is greater with speedy delivery of nicotine to the brain. The figure below[1] shows that presently only snus has an uptake profile that is close to that of cigarettes. However, Cobb et al (2009) found that some non-combustible PREPS available on the market (including some US snus products) delivered less nicotine than cigarettes and thereby failed to suppress tobacco abstinence symptoms as effectively as combustible products.

The shaded opportunity space between cigarettes/snus and nicotine chewing gum in the figure below shows where new and purer nicotine products will probably come.

[1] The figure is from the presentation "Product innovation and tobacco harm reduction (need for a more holistic regulatory framework)" by Adrian N Payne, UK, held at the ICAA's 51st Conference on Dependencies, Limassol, Cyprus 2008.



In 2001, the Institute of Medicine maintained that most PREPs – with the exception of nicotine chewing gum, which came on the market in the USA in the 1980s – had been used for too short a time to be able to draw reliable conclusions about their risk-reducing effects. However, the Institute meant that the so-called surrogate end-products, that is biochemical markers associated with smoking-related diseases, could be used as indicators of the health risks, and that this gave reason to believe that the transition from cigarettes to PREPs could lead to a substantial health gain (IM 2001). A trustable tobacco-prevention worker claimed that if the 1.3 billion cigarette smokers in the world had obtained their nicotine dose from so-called clean delivery systems instead of inhaling tobacco smoke, nicotine use would probably have been as low on the priority list for state intervention as use of caffeine (Sweanor et al 2007: 71).

4.1 Different understanding of the problem in England and Scandinavia

However, the problem is that PREPs have not been particularly demanded by smokers (see Chapter 7.1), probably because nicotine is taken up in the blood too slowly, the products are not designed to be attractive, and, unlike cigarettes, they do not have an identity-formative function, and do not play a role in self-presentation processes. Therefore, in England,

Cancer Research UK (CRUK), the British Heart Foundation and Action on Smoking and Health (ASH) have recommended that commercial production of new and "faster" nicotine products that can compete with cigarettes should be encouraged (CRUK 2008). The idea is to give these products the same or better conditions for competition than cigarettes, to put duties on these products in relation to the relative risk they represent, to correct misconceptions about the relative risk between cigarettes and other nicotine products, and to make the new nicotine products more attractive, socially acceptable and available. To *enable smokers to switch to less harmful products* is one of the five elements of the core aims of tobacco control (s10)[2].

> *"Currently, pure nicotine products are not attractive to smokers as direct replacements for cigarettes as they do not mimic the speed and intensity of nicotine intake that a cigarette provides. Regulation difficulties inhibit the development of more efficient and effective pure nicotine products. As a result, the most toxic nicotine products – cigarettes – are barely regulated while the safest products – medicinal nicotine – are highly regulated. If they are to compete with tobacco products, pure nicotine products must be sold on equal terms or better: pricing should favor pure nicotine products over tobacco. Public education is also needed as many smokers (and health professionals) have a poor understanding of the relative safety of pure nicotine products including nicotine replacement therapy".*

There is clearly an enormous gap between the recommendations of the English expert group and present Norwegian tobacco policy. Examples of this are i) a regulation that bans new nicotine products, ii) a strategy document without a discussion of harm reduction (SHDIR 2005), iii) up until recently opposition to use of snus expressed by the authorities, even for nicotine-dependent smokers with repeated unsuccessful attempts to stop smoking (Huseby & Klepp 2007, Holm et al 2008) and iv) refusal to grant dispensation for sale of electric cigarettes

The differences between the Norwegian and the English points of view about harm reduction illustrate that the parties have completely different understandings of the problem (see Chapter 8).

[2] The others are: helping smokers to quit, reducing exposure to secondhand smoke, preventing people from starting to smoke and reducing health inequalities.

4.2 Competition between the pharmaceutical industry and the tobacco industry

The most fundamental issue in the harm reduction debate is how much the different products reduce the hazards to health, and which products should be included in the range. In the 1960s, the tobacco industry marketed filter cigarettes as a harm-reducing alternative to cigarettes without filter. "Light" or "mild" cigarettes with reduced content of nicotine, tar and carbon monoxide were launched as harm-reducing products in the 1980s. The observation time for these products has been long, and over time epidemiological research has been able to show that the transition to filter cigarettes, light cigarettes and mild cigarettes has had little, if any, health gain (IM 2001). This negative experience has led to a great degree of scepticism to new products from the tobacco industry that are claimed to be harm-reducing. In the 1990s, the industry launched cigarettes on the American market (Eclipse, Premier, Accord) that, by burning at a lower temperature, should emit less poisonous substances. Because of low demand, these products were withdrawn from the market after a short time, and the harm-reducing effect was never examined.

A more promising approach to harm reduction was the development of medicinal nicotine products and certain types of smoke-free tobacco. Reviews of the literature show that medicinal nicotine products are not associated with large negative health effects (IM 2001, RCP 2007). Despite earlier opposition from certain people in the field of health, who found it difficult to accept the idea that nicotine should be used to treat smoking addiction, these medicinal nicotine products were eventually recommended as a type of treatment in Scandinavia. The English guidelines for medicinal nicotine products actually suggest use of these products by people in "vulnerable" groups, such as heart patients, pregnant women and young teenagers. (ASH 2005).

The pharmaceutical industry has now been accepted as an ally in the battle against smoking, and has contributed, with its research, to "un-demonize" nicotine. The industry's prominent position is reflected, for example, by its flamboyant presence at international tobacco conferences, where it is given the opportunity to present its research on products. With its resources, the pharmaceutical industry has to a large degree contributed to setting the agenda for choice of research issues in tobacco addiction research, perhaps with the result that certain other areas have been displaced.

As we shall point out in Chapter 7, medicinal nicotine products are not particularly popular among smokers, despite the long time they have been established, widespread marketing, easy availability and recommendations from the health authorities. This is related to the fact that they have deliberately been designed not to be too attractive to avoid misuse. For example, the first generation of nicotine chewing gum was made with an unpleasant taste in order for it to be authorized for the market. In addition, the products have had strong competition from the tobacco industry's new variety of snus with greatly reduced content of tobacco-specific nitrosamines (low TSN snus). This is the dominant type of snus in Scandinavia. In contrast to the earlier method of production, the tobacco in low TSN snus is heat treated, pasteurized and kept in cold storage until it reaches the consumer (read more about the production process on the web site of GothiaTek: www.gothiatek.com).

In countries where snus is allowed to be sold (for example in Sweden and Norway), it seems that this product has higher user potential and 'likeability' among smokers than medicinal nicotine products. Studies have shown that snus is used both as a method of treating smoking addiction and as a smoking substitute, for example for use in places where smoking is not allowed. The quit smoking campaigns run by the authorities and introduction of more and more smoke-free public places (for example places where food and drinks are served) have thus led to an increase in the use of snus.

The snus industry, not surprisingly, emphasizes that low TSN snus has characteristics that medicinal nicotine products do not have in order to be effective harm-reducing products. Low TSN snus is popular, and provides a nicotine dose that is almost the same as for cigarettes but with a significantly reduced health risk. In addition, use of snus (choice of brand, aesthetic use rituals, visibility) gives a basis for social positioning and self-presentation (Nordby & Wood 2008). Snus, in contrast to nicotine chewing gum and nicotine patches, has identity-forming functions of use identical to those of cigarettes. Therefore the industry believes that use of snus represents so far the most promising solution to today's smoking problem. Snus is the only product on the market that can compete with cigarettes. The industry chooses to under-communicate the fact that snus, in contrast to medicinal nicotine products, leads to the same nicotine dependency as cigarettes. Or else they emphasize that nicotine (nicotine dependence) per se does not represent a significant health risk.

Because of many previous doubtful contributions (Glantz et al 1996), the tobacco industry struggles with low credibility in the harm reduction debate. Even Swedish Match, the main supplier of snus to the Scandinavian market, is regarded as part of the tobacco industry, and their views are automatically met with scepticism[3].

[3] Swedish Match does not produce cigarettes, but uses its distribution system to supply tobacco dealers in Sweden (but not in Norway) with cigarettes from other producers.

5 Can Swedish snus be included as a harm reduction product?

5.1 Harm reduction at the individual level

Because low TNS snus has taken the lead as the most relevant harm reduction alternative to cigarettes, there has been much medical research on its health effects. The EU Commission (SCENIHR 2008) and IARC (Cogiliano et al 2004) appointed committees to carry out reviews of the literature about research on use of snus and its health effects. Similar reviews have also been carried out by expert committees appointed by the authorities in Norway (Dybing et al 2005), Sweden (Cnattingius et al. 2005) and New Zealand (Broadstock 2007). In several studies, the central theme has been to compare the health effects of low TNS snus and cigarettes. The most systematic comparative analysis was carried out in 2008 by the *Scientific Committee on Emerging and Newly Identified Health Risks* (SCENIHR), commissioned by the EU Commission. The Committee examined every group of diseases for which cigarette smoking has an effect, and compared the health effects from smoking and from use of snus. The differences turned out to be extremely large:

> ***Respiratory disease:*** *Respiratory diseases, predominantly lung cancer, COPD and pneumonia, account for 46% of the deaths caused by cigarette smoking in the EU. There is no consistent evidence that any STP (smokeless tobacco product) causes any of these major respiratory diseases. Complete substitution of STP for tobacco smoking would thus ultimately prevent nearly all deaths from respiratory disease currently caused by smoking, which in total represent nearly half of all deaths caused by smoking.*
>
> ***Cardiovascular disease****: Cardiovascular disease accounts for 28% of deaths caused by smoking in the EU. For snus, several published studies provide estimates of relative risk for both snus and smoking in the same populations, and all indicate that the risk of snus use is less. It is therefore reasonable to draw a conservative conclusion that substitution of smoking by snus use would, in due course, reduce the cardiovascular mortality that currently arises from tobacco use by at least 50%*[4].

[4] Since the release of the SCENIHR-report, three epidemiological studies on snus and risk for cardiovascular disease have come out from Sweden (Hansson et al (2009), Åmgman & Eliasson (2008), Janzon & Hedblad (2009). None gave support to any strong association between snus use and risk for cardiovascular disease.

> ***Oral and GI cancer***: *Although responsible for relatively few deaths in comparison with the above causes among smokers, the combined risk of oral and pharyngeal, esophageal or pancreatic cancer is increased by smokeless tobacco use and are therefore important to consider. Thus it is evident that the risk of pancreatic cancer associated with snus use is less than that of smoking, and for oral cancer substantially so. Since the number of deaths from these diseases is relatively small, the public health impact of this reduced risk, if snus were to replace smoking, would also be modest.*
>
> ***Passive smoke effects***: *Since STPs do not produce smoke they will not cause any of the health problems linked to passive smoke exposure in adults or children. Substitution of snus for smoked tobacco would therefore prevent the passive smoke-related diseases.*

The report concluded:

> *Overall therefore, in relation to the risks of the above major smoking-related diseases, and with the exception of use in pregnancy, STPs are clearly less hazardous, and in relation to respiratory and cardiovascular disease substantially less hazardous, than cigarette smoking. The magnitude of the overall reduction in hazard is difficult to estimate, but as outlined above, for cardiovascular disease is at least 50%, for oral and GI cancer probably also at least 50%, and for respiratory disease close to 100%.*

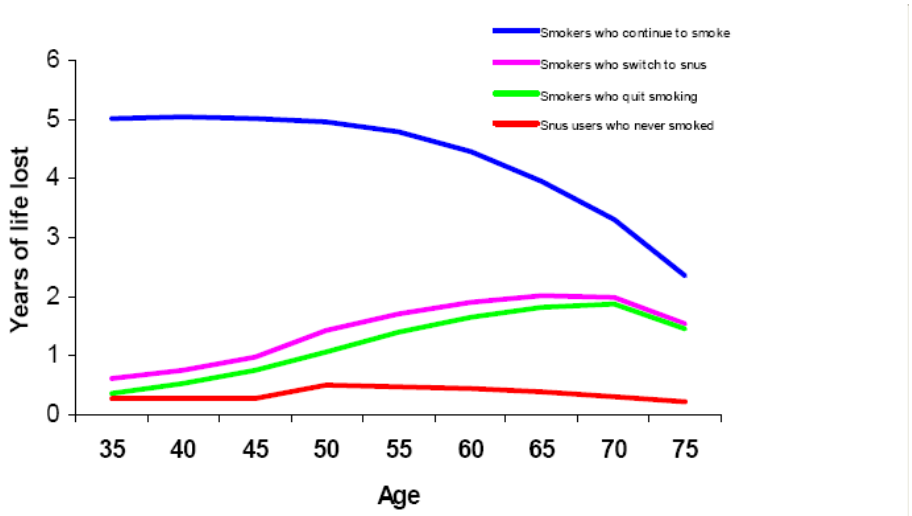
The Royal College of Physicians (2007), a prestigious scientific institution in the British Medical Association, carried out a comparison of cigarettes and snus the year before, and came to a similar conclusion:

> *Therefore, in relation to cigarette smoking, the hazard profile of the lower risk smokeless products is very favourable (RCP 2007: 161).*

A study based on a modified Delfi design[5] concluded that the total health risk associated with use of snus was most probably at least 90 per cent lower than with smoking. Among other things, the expert group meant that the risk associated with use of snus compared to smoking was 70-85 per cent lower for oral cancer, 97-98 per cent lower for lung cancer, and 90 per cent lower for cardiovascular disease (Levy et al. 2004). A simulation model based, among other things, on these estimates of risk,

[5] A method of evaluation by an expert group, which is used when the basis for making a decision is not very robust.

was recently published in The Lancet, and showed that the switch from smoking to snus did not represent a large difference in survival compared with smokers who gave up all use of tobacco (Gartner et al. 2007).



. **Estimated years of life lost by male smokers, male smokers who quit smoking, male smokers who switch to snus, and male snus users. Drawn on the basis of data from Gartner et al. (2007)**

More precisely, Gartner et al. (2007) found that the number of lost years of life attributable to use of tobacco for 40-year-old men was 5.04 for smokers who continued to smoke, 0.53 years for smokers who gave up all use of tobacco, 0.77 years for smokers who switched to snus, and 0.28 years for snus users who had never smoked.

Henley et al. (2007) analysed data from the large American Cancer Society Cancer Prevention Study II. After 20 years' follow up, smokers who had switched to smoke-free tobacco (of the American type), had a negligibly higher risk of death than smokers who gave up all use of tobacco (HR 1.08, 95% confidence interval 1.01-1.15). American snus is not produced according to the standards of GothiaTek, and has a substantially higher content of harmful substances than the types of snus that are used in Norway and Sweden (Stepanov et al. 2008).

There is little discussion in professional circles about the great harm-reducing effects for individuals of switching from cigarettes to snus. However, there has been considerable disagreement about the effect that

availability of snus can have at the population level. A central issue that is discussed in relation to this is whether removing the ban on sale of snus in the EU would result in a loss or a gain for public health (SCENHIR 2008).

5.2 Harm reduction at the population level

In order to calculate the net effect for public health, the task has to be operationalized into at least 10 questions

i) Smoking cessation
   a. How many smokers who otherwise would never have been able to quit smoking would be able to do so with snus?
   b. How many smokers who otherwise would have been able to quit using tobacco completely, would begin to use snus instead?
   c. How many smokers who quit smoking with the help of snus, continue to use snus?

ii) Combined use:
   a. Would availability of snus result in combined use of snus and cigarettes?
   b. Does combined use represent a temporary, passing phase towards smoking cessation?
   c. Does combined use of snus and cigarettes involve reduced smoking intensity, and would this reduction be so large that it would have an influence on health?

iii) Recruitment:
   a. Would we get snus users who would otherwise never have begun to use tobacco?
   b. Would snus lead to subsequent smoking initiation (gateway)?
   c. Would young people who otherwise would have begun to smoke begin to use snus instead (immunization)?

iv) Extrapolation
   a. Can the net effects observed in one country, for example Sweden, be extrapolated to other countries that do not have the same history of use of snus (for example Germany)?

Obtaining reliable answers to these questions is a great challenge for research, which requires, at the very least, observational data (natural non-controlled experiments). Therefore, empirical studies of tobacco behaviour in Norway, Sweden and parts of the USA, where use of snus is

allowed and widespread, have received special attention internationally. We now experience the same interest in our data as we did when Norway was one of the first countries in the world to introduce a total ban on advertising of tobacco products (1975), and a total ban on smoking in places that serve food and drinks (2004).

SIRUS (The Norwegian Institute for Alcohol and Drug Research) is cooperating with Swedish and American researchers in order to find answers to these questions. The Institute has employed PhD students, who work with several of these research questions, and who have collected extra data to illuminate these issues, in cooperation with the Norwegian Directorate of Health. In articles published in English, results based on Norwegian data will be presented, but this will be some time in the future. In the meantime we present the opinions of the tobacco experts on the net effect of snus – opinions based more on logical reasoning, simulation models and ecological aggregated data than on empirical testing of the ten questions given above.

5.2.1 Tobacco-related morbidity and mortality in Sweden

Sweden, where tobacco consumption per consumer is slightly higher than in Norway, but where, for a long time, half the tobacco (58 per cent in 2007) has been consumed as snus, has the lowest tobacco-related mortality in the western world (Peto et al. 2005). Tobacco-related mortality has fallen in line with increased use of snus. A calculation made in 2004 showed that there would have been 200 000 fewer tobacco-related deaths among men in 15 EU countries if tobacco habits in these countries had been "Swedish" (Rodu & Cole 2004). The proportion of Swedish women smokers has been about the same as in other EU countries, and this has been reflected in a somewhat similar mortality in these countries. In several articles, the Swedish nicotine researcher Karl-Olov Fagerström has argued that availability of snus has resulted in a net health gain in Sweden (Fagerström & Schildt 2003).

5.2.2 Risk/use equilibrium

One concern with harm-reduction products is that they may be used by people with no previous experience with nicotine, or by people who would have managed to quit smoking by other means. If there are many such people, this could result in a net loss for public health. A method of assessing this, called risk/use equilibrium, addresses this aspect of harm reduction. The method is based on the size of the risk reduction at the

individual level by switching, for example, from cigarettes to low TSN snus (about 90 per cent), and estimates the number of new snus users that are needed in order to produce a net loss at the population level. The research that has been carried out so far (Gartner et al. 2007) shows a scenario where the number of new users of snus must come up to completely unrealistic proportions in order to offset the positive effect of each smoker who switches to snus.

> *"For net harm to occur, 14-25 ex-smokers would have to start using snus to offset the health gain from every smoker who switched to snus rather than continuing to smoke. Likewise, 14-25 people who have never smoked would need to start using snus to offset the health gain from every new tobacco user who used snus rather than smoking. Current smokers who switch to using snus rather than continuing to smoke can realise substantial health gains. Snus could produce a net benefit to health at the population level if it is adopted in sufficient numbers by inveterate smokers. Relaxing current restrictions on the sale of snus is more likely to produce a net benefit than harm, with the size of the benefit dependent on how many inveterate smokers switch to snus"* (Gartner et al. 2007.)

5.2.3 Empirical studies of the gateway hypothesis

In Norway, recruitment of snus users among young people with no previous experience of smoking is increasing. A potential health gain could be obtained if use of snus by people in this age group immunized them against starting to smoke later. If instead, the new popularity of snus leads to recruitment of users of tobacco who would otherwise not have begun to use tobacco at all, in the long term this could lead to a health loss at the population level. We risk a substantial reduction in public health if many of the young snus users after a while begin to use cigarettes, either in addition to snus or instead of snus. The question is whether use of snus in such cases can be regarded as a gateway to smoking (the gateway hypothesis). If this is the case, one must be able to demonstrate that young people who switch to smoking would not have done so if it had not been for their experience of use of tobacco gained from their previous use of snus. Alternatively, it may be that young people who would have begun to smoke anyway (those who are predisposed), for different and maybe random reasons have a temporary start phase with use of snus. In this case, use of snus cannot be regarded as a gateway.

A heated debate about this area has been going on for a while (O'Connor et al., 2003; Kozlowski et al., 2003; Tomar & Loree, 2004). In the

international research literature, the need for testing the stepwise hypothesis with data that gives the possibility to draw causal conclusions, has been expressed.

However, there are some things we already know. The group of snus users who began to use snus and started to smoke cigarettes later – "potential causal users" – represent only a small minority of present-day snus users. The majority of snus users are "non-causal users", because they either do not smoke in addition to using snus, or else they began to smoke before they began to use snus. This indicates that any gateway effect must be modest. However, the concern is that the mean debut age for snus is going down, while the debut age for smoking is more or less stable. At the same time, the proportion of snus users is increasing while the proportion of smokers is decreasing. These mechanisms mean that the number of potential causal users will increase. In other words, more and more people begin to use snus at an increasingly earlier age, while increasingly fewer young people begin to smoke. If a gateway effect from snus to cigarettes exists, its effect will be strengthened under these conditions.

Several longitudinal studies (Galanti et al., 2001, 2008; Tomar, 2003; Ary et al., 1987; Haddock et al., 2001, Furberg et al. 2005, 2008, Timberlake et al 2009) and retrospective studies (Ramström & Foulds 2006, Kozlowski et al. 2003, Tomar et al., 2004; Peterson et al., 1989) have been carried out, which have addressed the question of whether snus increases the probability for subsequent smoking initiation. The empirical basis indicates that this can be the case only to a small degree. In the SCENIHR report, the research is summarized as follows:

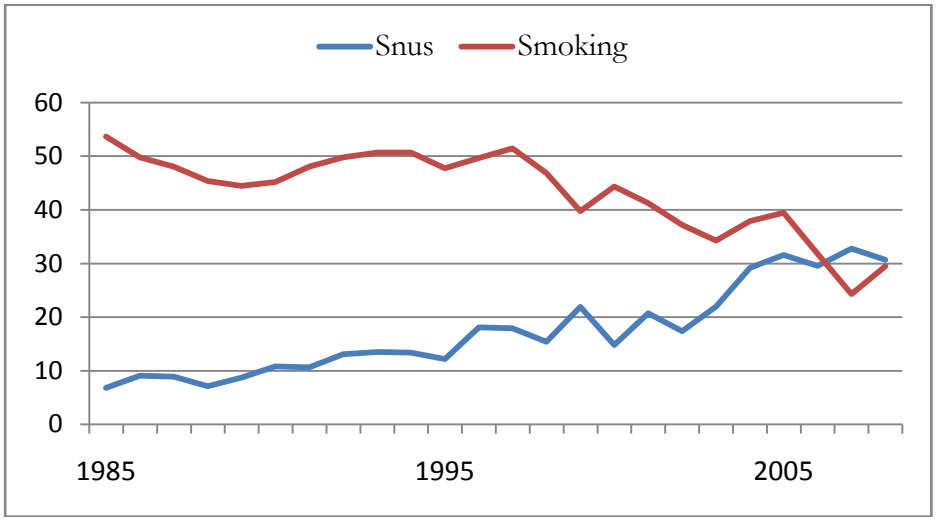
> *"No systematic reviews have been published on the subject. The Swedish data, with its prospective and long-term follow-up do not lend much support to the theory that smokeless tobacco (i.e. Swedish snus) is a gateway to future smoking. In the USA, the interpretation of two studies is divergent. The marked social, cultural and product differences between North America and Europe, suggest caution in translating findings"* (SCENIHR 2008:108).

It is worth noting that no research design up until now has addressed the question of a gateway effect with more stringent requirements for causality than the requirement to identify an increase in probability. An ambition for research should be to contribute knowledge on the basis of research design with more stringent requirements for causality. First, spuriousness should be controlled for (for example, only thre studies have models with

psychosocial background variables). Second, it is important to identify underlying mechanisms that could link the statistical correlation between snus and future smoking. Finally, one should be able to demonstrate that young people who start smoking would not have done so if they had not had user experience with tobacco that they had gained from previous use of snus.

If snus had had *great importance* as a gateway to smoking, a logical consequence would be that the dramatic increase in use of snus among young men would subsequently lead to an increase in smoking. However, the figure below shows a marked reduction in smoking among men in the age group 16-24 years in Norway. Though it is still possible that use of snus increases the risk of smoking for *some* people.

Use of cigarettes and snus (daily + occasionally) among men in the age group 16-34 years in Norway 1985-2008.
Source: Statistics Norway



5.2.4 Empirical studies of snus at the cessation of smoking

Several Swedish (Rodu et al. 2002, 2003, Lindström et al. 2002, Gilljam & Galanti 2003, Stegmayr et al. 2005, Ramström & Foulds 2006) and Norwegian studies (Lund et al. 2007, Lund et al. 2008b) have shown that the quit rate for smoking is higher for present and former snus users than for smokers with no experience of use of snus. This indicates that use of snus increases the probability for being able to stop smoking. This does not of course mean that use of snus is a *necessary* or *sufficient* condition for smoking cessation.

The exception is occasional snus users in Norway, for whom the quit rate for smoking is low. This is probably because occasional snus users – who account for about one half of snus users in Norway – also use snus for reasons other than stopping smoking completely (for example, smoking substitution when in smoke-free places). It may also be that occasional snus users at the time of the interview were still in a temporary transition stage on the way to total smoking cessation. These are issues that will be studied further by SIRUS researchers. In Sweden, where the snus epidemic is at a more advanced stage, the proportion of occasional snus users is lower than in Norway. This may indicate that there will be fewer occasional snus users when the "snus epidemic" has a longer history.

In the SCENIHR report, the following conclusions were made about the role of snus in smoking cessation:

> *"Observational data from Sweden indicate that snus has been used more often than pharmaceutical nicotine products by some men as an aid to stop smoking. The data are consistent in demonstrating these male snus users are more likely to quit smoking than non-users. In these uncontrolled, retrospective studies, results on par with those achieved with nicotine replacement products and above, are quoted. A side effect, however, is that 60% or more smoking abstainers become chronic snus users. There are no published randomised clinical trials of use of smokeless tobacco in smoking cessation, and in the absence of such evidence it is not possible to draw reliable conclusions as to the relative effectiveness of smokeless tobacco as an aid to clinical smoking cessation in comparison with either placebo or other established therapies"* (SCENIHR 2008: 110).

The report concluded that i) snus is used more often than nicotine replacement products for quitting smoking, ii) snus users have a higher quit rate for smoking, iii), many people who had successfully quitted smoking by using snus were still snus users at the time of the study, and

iv) due to insufficient evidence it is not possible to draw conclusions as to the relative effectiveness of smokeless tobacco as an aid to smoking cessation in comparison with established therapies.

In Norway, Erik Dybing, Director of Division in the Norwegian Institute of Public Health, speedily informed the general public of his interpretation of the SCENIHR report. In a newspaper interview, and on the Institute's web site, he stated:

> *"There is no scientific basis for recommending snus as a useful aid for smoking cessation".*

Maybe it was intentional – maybe it was unintentional – but the semantics in Dybing's message allowed an interpretation that in no way was in accordance with the conclusion in the report: that at present there is insufficient evidence to compare the relative effectiveness on smoking cessation of snus and nicotine replacement therapy.

The message of the Norwegian Institute of Public Health / Dybing could just as well have read: *science has spoken, and has found out that snus is not a useful aid for smoking cessation*. The articles that subsequently appeared in the media indicated that this was exactly how journalists had decoded the message. A telling example was the headline in the online newspaper "Nettavis": "*Snus can in no way be used as an alternative to stopping smoking*"

A future research task that will be given priority by SIRUS is to develop a more sound knowledge base about the effect that use of snus has on smoking cessation compared to other methods.

5.3 Can snus be regarded as a harm-reducing product?

Despite the fact that snus probably increases the risk of cancer of the pancreas and oesophagus (Bofetta et al. 2008, SCENIHR 2008) (though the increase in risk is much lower than for cigarettes), the results of research are clear: Snus is a substantially less hazardous source of nicotine than cigarettes. There is thus a clear gain at the individual level, but there is still some uncertainty about the exact net effect at the population level. With the pattern of use of snus in Sweden and Norway, the net effect must be positive, at least in these countries. However, some researchers

have pointed out that cultural differences in other countries weaken the value of extrapolating the results of experience to other countries (Chapman & Freeman 2007, SCENIHR 2008). For example, Shu-Hong et al. (2009) have used empirical data to argue that the transition from smoking to snus that has been observed in Sweden (and Norway) does not seem to have been found in the USA. The Swedish tobacco researcher, Lars Ramström, commented the findings of Shu-Hong:

> *The main conclusion "The Swedish results are not replicated in the U.S." is certainly true, but not very interesting since it just lays down something very obvious. Sweden's last 50 years' development of increasing snus use is built on quite old Swedish traditions and could not possibly have been replicated in a country where Swedish type moist oral smokeless tobacco has not until recently been available altogether and misleading pieces of discouraging information have dominated over evidence-based statements regarding the characteristics of the product (Ramström 2009).*

The American Association of Public Health Physicians states very clearly that tobacco products such as snus should be included in the arsenal of products for harm reduction:

> *"While some have proposed limiting harm reduction to medicinal nicotine products, such a limitation would likely place the reduced risk out of reach of rebellious teens, socially disadvantaged minorities, gays and other high risk groups. We are therefore recommending that the approach to harm reduction be based on tobacco products sold in the same retail outlets as cigarettes, and at comparable prices" (*AAPHP 2008: 3).

If we accept the view of the public health physicians in the US, it is appropriate to ask the following question: Given that the aim of state tobacco control policy is to reduce tobacco-related mortality in Scandinavia, and not to eliminate use of tobacco per se, should the authorities then have a more pragmatic view of the role that snus can play for achieving this aim?

A somewhat more "capitulating" view about snus as a harm-reducing product was recently expressed by a group of English researchers. In the article *"The place for harm reduction and product regulation in UK tobacco control policy"*, the authors first acknowledge that lifting the ban on snus in England would probably lead to a marked reduction in tobacco-related morbidity and mortality. But because there is such a high level of disagreement in health circles about the issue of snus, and this distracts attention from the work against tobacco, the researchers recommended

that snus should be excluded from the discussion about acceptable harm-reducing products for the time being (Gilmore et al. 2008). The researchers thus accepted the consequences of the fact that the status of knowledge about snus as a harm-reducing product is still in a pre-paradigm period of scientific thought[6] without scientific consensus (Kuhn 1970), and so they chose the path of least resistance.

[6] According to Kuhn (1970), science develops in leaps (revolutions). Before there is scientific consensus about the most appropriate theories and methods, there is a pre-paradigm period, when several different schools of scientific thought exist in parallel and in competition with each other.

6 Lack of tailor-made measures for the remaining smokers

People in the remaining group of daily smokers in Scandinavia are greatly over-represented by people with short education. In a Norwegian study of smoking and social inequalities in 2005, Lund & Lund (2005) concluded:

> *"The study confirms that smoking now remains as a behaviour related to social class and affiliation. The typical smoker is a middle-aged, divorced man, he votes for the Progress Party, he is from Northern Norway, has a short education, a low paid job in industry or is unemployed… In addition, smokers from lower social classes have higher smoking intensity, more often use the most hazardous tobacco products, have a lower debut age, have greater acceptance of passive smoking, fewer of them have rules to limit smoking in the home, and they are more often misinformed about the health risks of the different types of tobacco…. The social gradient in smoking represents a great challenge to achieving the aim of reducing future inequalities in health status in the population. There is a need for interventions aimed specifically at the lower social classes, but the knowledge base for developing such measures is weak".*

The Norwegian public health physician, Per Fugelli (2003), has expressed concern that health prevention produces stigmatization, by repeatedly selecting underprivileged groups and marketing their misery without being able to do very much about it. This view is supported by other authorities concerned with health policy:

> *"A cunning form of humiliation of the lower social classes is practised by people who work with modern health education…. They use the mass media in health education campaigns to give an underlying message that sick people and poor people understand: "You are not just sick and poor, you are also stupid". In this way, health informers can weaken people's self-image.*
> (Gulbrandsen 2003: 118-32).

6.1 How large is the hard-core of intransigent smokers?

Many smokers are in a life situation in which managing to quit cigarettes is probably experienced as difficult. It was probably easier to modify the behaviour of the population of Scandinavian smokers that was the target group for the preventive measures used in the 1970s and 1980s, than to

change the behaviour of the group that is left today. In research on smoking behaviour, there is a hypothesis – the hardening hypothesis – that we will be left with a group that is steadily more difficult to influence as the prevalence of smokers decreases. This is partly because a minority of the people in this group, for different reasons, actually wish to continue to smoke, and also because some of them, despite the fact that they wish to quit smoking, cannot manage to do so because they are heavily addicted to nicotine[7].

With support from the Research Council of Norway for the period 2009-2011, The Norwegian Institute for Alcohol and Drug Research (SIRUS) shall start a PhD project with the aim of studying the hardening hypothesis more closely. When will we come up against a hard core of smokers who are almost untouched by the traditional state interventions? Presently, the proportion of smokers in the population is still falling, and preliminary analyses indicate that we still have a way to go before we reach rock bottom – the hard core smokers – if they exist at all. It is perhaps not until the reduction in the proportion of smokers stops that harm reduction will really become relevant as an alternative action policy? Therefore, knowledge gained from the "hard core project" will probably be relevant as the basis for the authorities to make decisions about harm reduction policy.

One way of identifying smokers for harm reduction measures is to select smokers with many unsuccessful attempts to quit. In Norway, 45 per cent of smokers have had three or more, and 20 per cent have had five or more unsuccessful attempts (aggregated data for the period 2003-2007, n=1192). Another way of identifying this group is to use the answers to several questions, for example questions about smoking intensity, intention to quit, and previous attempts to quit. Using this method, it was found that 16 per cent of daily smokers in Norway were hard-core smokers (Lund 2006).

Irrespective of the definition criteria, a relatively large group of smokers in Scandinavia are either unable or unwilling to quit smoking. By starting to smoke in their teens and continuing to smoke after the age of 35, these

[7] Nicotine addiction is characterized by, among other things, increased motivation for repeated use, development of tolerance for certain substances, and withdrawal symptoms after quitting that range from negative mood and depression to physical discomfort.

people have a 50 per cent chance of dying of a smoking-related disease. Harm reduction must be seen with this perspective.

However, it is important to stress that the transition to less hazardous nicotine products will affect *all* present and future smokers – not just those who are "at rock bottom".

6.2 The social gradient and adapted measures

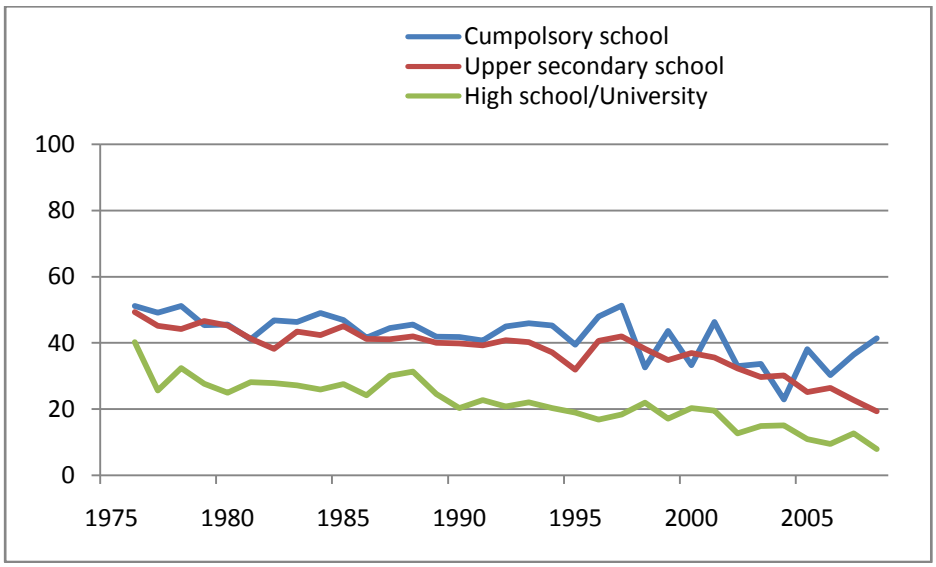
The social gradient we see in today's pattern of use has been observed for many decades in countries that have the most advanced position regarding the spread of smoking, including the Scandinavian countries. The search for tailor-made measures for smokers who, for example, have short education, has been going on for a long time. Literature reviews in this area have not identified measures that the authorities have been able to implement in order make the social gradient in smoking pattern less steep (Sørensen et al. 2004) (perhaps with the exception of tobacco duties) (Thomas et al. 2008, Main et al. 2008). The report from the Norwegian Knowledge Centre for the Health Services – *Measures to reduce smoking, particularly in groups with low socio-economic status* (Steiro et al. 2007) – is an example of this. The report concluded that most interventions had better effect on the higher social groups:

> *"A thought-provoking result from this summary is that several studies have shown better results for groups with high income and education. This means that the differences between the socio-economic groups will become greater"* (Steiro et al. 2007: 5).

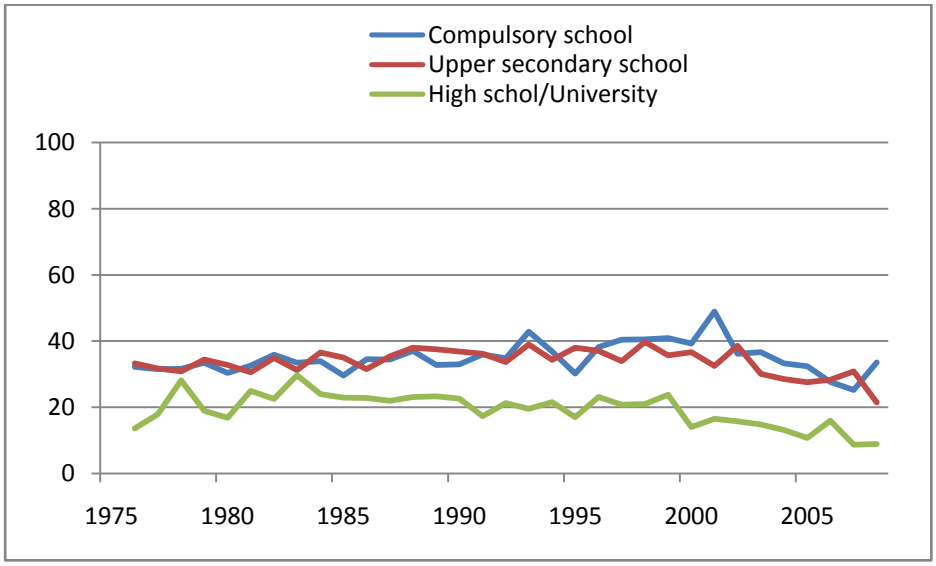
This finding is consistent with results from a systematic summary of the differences in the effect of anti-tobacco media campaigns in different social classes. Most often, the campaigns were most effective for smokers with long education and high income (Niederdeppe et al. 2008). Based on studies carried out in the USA, Canada, Australia and Western Europe, the conclusion was:

> *"We find that there is considerable evidence that media campaigns to promote smoking cessation are often less effective, sometimes equally effective, and rarely more effective among socioeconomically disadvantaged populations relative to more advantaged populations"* (Niederdeppe et al. 2008: 1343).

The proportion of daily smokers according to educational level, Norwegian men, 1976-2008



The proportion of daily smokers according to educational level, Norwegian women, 1976-2008



6.3 Problem behaviour and mental disorders among remaining smokers

Recent research has shown that the group of remaining smokers in western countries is characterized by other problem behaviours (the problem behaviour syndrome), and of mental disorders such as schizophrenia, depression, attention-deficit/hyperactivity disorder (AD/HD), Tourette's syndrome, bipolar disorder and anxiety. We have no exact overview of the actual size of this group of smokers in Scandinavia. However, in the USA it has been calculated that 44 per cent of total tobacco consumption is used by people with "*past month mental disorder*" (Lasser et al. 2000). Ken Warner (2007) maintains that smoking in this sub-group should not only be understood in the light of addiction and construction of identity. The motive can also be self-administration of nicotine (and perhaps other chemicals) to treat a co-morbid condition. The sub-group of people with mental disorders – estimated to be 20-40 per cent of smokers (Warner 2007) – come in addition to those who have no such serious conditions in addition, but who continue to smoke against their own will.

> *"In my judgement, the most important fact about today's smokers is that many of them – perhaps as many as half – are suffering from some form of mental illness or other substance use. As a group they find quitting more difficult, and perhaps of less interest. Increasingly, tobacco-control policies and smoking cessation treatments must focus on addressing the needs of this growing population who smoke to deal with a variety of problems that may have had little relevance to previous generations of smokers who quit relatively easily".* (Warner 2007: 315).

6.4 The precautionary principle

As pointed out several times in this report, there is no doubt that use of snus, and to a lesser degree medicinal nicotine products, involves a certain risk to health. The health authorities, particularly in Norway, have therefore on several occasions called for a precautionary principle approach ("better-safe-than-sorry"), particularly in relation to snus as a harm-reducing product. Along with most of us, they are concerned that i) acceptance of snus as a product for treating smoking addiction for established smokers would lead to normalization of use of snus among young people with no previous experience of smoking. This concern is combined with the recognition that ii) the exact long-term effects of use

of low TSN snus are not yet certain for young people who began to use snus early in life, because of the short observation time. Before we know what the long-term consequences are, we should not recommend snus as a harm-reducing alternative to cigarettes, according to the precautionary principle.

Others would maintain that it is worth taking this risk, because present knowledge indicates that the benefits gained would nevertheless be much greater than the damage caused (Gray 2004). During the period when the authorities have a precautionary principle approach, and continue to exclude harm reduction from their strategic plans, we take the risk that very many people will become ill and die unnecessarily. To "sit on the fence" with a "better-safe-than-sorry" approach until everything is "cut and dried" will maintain the status quo, in which tens of thousands of Scandinavians continue to die each year.

Advocates of the precautionary principle often demand extremely strong evidence for the harm-reducing effects of use of snus. However, because of the nature of the problem, it is impossible to carry out randomized controlled trials to find out exactly how large the reduction in risk is. Such unreasonable requirements for evidence were, of course, not made when knowledge about premature death as a result of smoking was being built up (Kozlowski et al. 2003). The results of epidemiological observational studies were regarded as an adequate basis for action/interventions. The requirements should be no different now.

7 Imbalance between the motive to quit created by society and assistance to quit

Scandinavian smokers now practise their behaviour in a very tobacco-hostile norm climate (Pedersen 2008). The symbolic content is negative, the habit can only be practised in restricted areas, repeated campaigns sustain pressure on cognitive information, and the price is high. In other words, "society" has created strong incentives to quit. About 75 per cent of Norwegian smokers have made repeated unsuccessful attempts to quit (Lund & Lindbak 2007), and nearly all smokers regret that they started (Fong et al. 2004). The question is whether the assistance that is offered to the remaining smokers – with their special characteristics – is adequate and effective. Research has shown that this is not the case

In the policy document from the five Nordic directors of health, referred to previously, it is stated that:

> *"Evidence-based methods for quitting smoking exist. The methods that are the most effective are a combination of support and medication"* (Holm et al. 2008: 3502).

However, a critical appraisal of the Cochrane reviews on effects, how long effects last, and studies of "real-world" implementation, can cause optimism to be moderated.

7.1 What effect do medicinal nicotine products have on the quit rate for smoking?

The answer depends on who you ask!

> *"You actually double your chance of quitting smoking if you use medicinal nicotine products".*
> *"By using NICORETTE® you double your chance to succeed, compared to if you just trust your willpower".*

The claims given above about a 100 per cent increase in effect have been made by the pharmaceutical suppliers of Nicorette and Nicotinell medicinal nicotine products.
(http://www.nicorette.no/Vare-produkter.aspx)
(http://www.nicotinell.no/)

This message is communicated in advertisements, is often repeated in newspaper articles, and has probably given many people the impression that use of medicinal nicotine products is very effective for quitting smoking.

However, the impression of the effect of medicinal nicotine products has been moderated by research. In a Cochrane review from 2008 (Stead et al. 2008) the authors concluded that nicotine chewing gum increased the quit rate for smoking by 58 per cent, while nicotine patches gave a 43 per cent increase in effect compared to a placebo.

> *"We identified 132 trials; 111 with over 40,000 participants contributed to the primary comparison between any type of NRT and a placebo or non-NRT control group. The RR of abstinence for any form of NRT relative to control was 1.58 (95% confidence interval [CI]: 1.50 to 1.66). The pooled RR were 1.43 (95% CI: 1.33 to 1.53, 53 trials) for nicotine gum and 1.66 (95% CI: 1.53 to 1.81, 41 trials) for nicotine patch".* http://www.cochrane.org/reviews/en/ab000146.html

The pharmaceutical industry maintain that:

> *"If you manage the first three months, the next three months are much easier. And after half a year, your chances of remaining smoke-free for the rest of your life are good!"*
> http://www.nicorette.no/Slutte-a-royke/Nikotinlegemidler.aspx.

Again, this statement is modified by scientific reviews. In the article *Nicotine replacement therapy for long-term smoking cessation: a meta-analysis* (Etter & Stapleton 2006), researchers focussed on the long-term effect on smoking cessation of the present NRT (nicotine replacement therapy) products. More precisely, they based their conclusions on the results of twelve studies with a total of 4 792 patients who had been followed up over a period of two to eight years after quitting smoking. After twelve months, with a mean use of NRT of 22 weeks, one out of twelve were still smoke-free, while after 4 years only one out of 19 were still abstinent. The conclusion was that the effect continued to fall by 30 per cent after the first year, and that tobacco dependence should therefore be regarded as a chronic disorder requiring repeated episodes of treatment.

> *"Results after only 6-12 months of follow-up, as used in existing reviews and treatment guidelines, will overestimate the lifetime benefit and cost-*

efficacy of NRT by about 30%. Because the long-term benefit of NRT is modest, tobacco dependence treatment might be better viewed as a chronic disorder, requiring repeated episodes of treatment".

As mentioned in Chapter 4.2, the pharmaceutical industry has financed much tobacco addiction research. The focus has most often been on the effect of their products, compared with a placebo or no treatment. Testing takes place in randomized controlled trials in a clinical setting, most often managed by a doctor. There has been less research to measure the effect of the products in a real-world setting. However, Pierce et al. (2002) pointed out that the results obtained in randomized controlled studies of medicinal nicotine products cannot necessarily be repeated in the real world when the products are bought in a shop. Cummings & Hyland (2005) studied the effect that the availability of NRT products has had on smoking behaviour in the American population. The conclusion was remarkable:

"Accumulated evidence from controlled clinical trials has demonstrated that available forms of NRT (e.g., gum, transdermal patch, nasal spray, inhaler, and lozenge) increase quit rates compared with placebos by 50%-100%. However, despite the positive results from these studies, fewer than one in five smokers making a quit attempt do so with the benefit of NRT. Because not enough smokers are using NRT, ***the availability of NRT has not had a measurable impact on influencing population trends in smoking behavior****. Among the factors contributing to the low utilization of nicotine medications are the inadequacies of the current dosage strengths and formulations of existing medications, smokers' perceptions of the high cost of the drugs, and concerns that many smokers have about safety and efficacy of nicotine medications".*

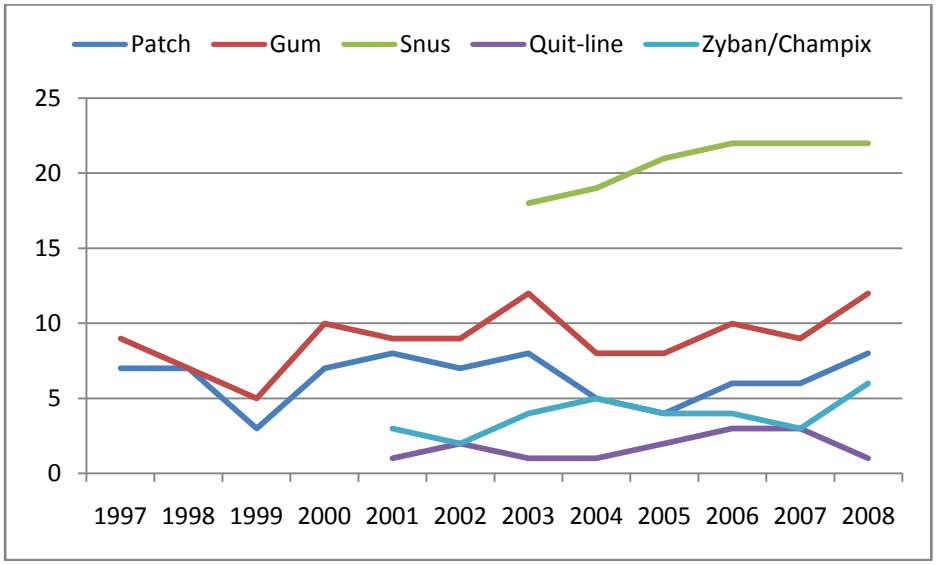
Even with the use of medicinal nicotine products, the relapse to smoking was extremely high, and no different from the relapse to use of opiates after treatment for drug addiction (US Surgeon General 1988). Hughes et al. (2004) showed that the majority of relapses to smoking occur during the first eight days.

In Norway, just under 30 per cent of smokers attempt to stop smoking each year (Lund & Lindbak 2007). The figure[8] below shows that only a small proportion of men who have quitted (successfully and unsuccessfully) used an NRT product, even though these products

[8] The black line shows the regression line for use of snus at smoking cessation.

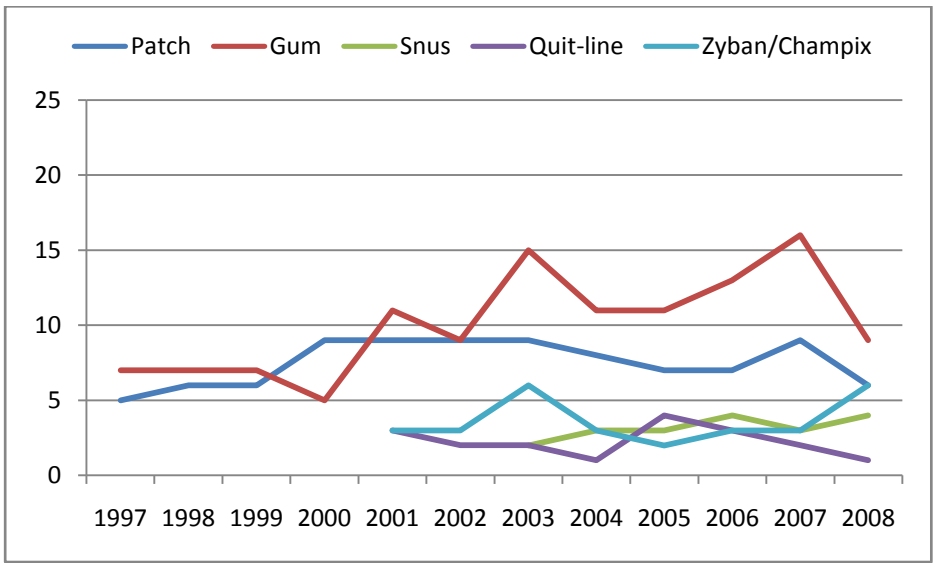
increase the probability for abstinence to a certain extent[9]. According to the statistics, of the approximately 90 per cent of daily smokers who try to quit each year begin again within 6 to 12 months.

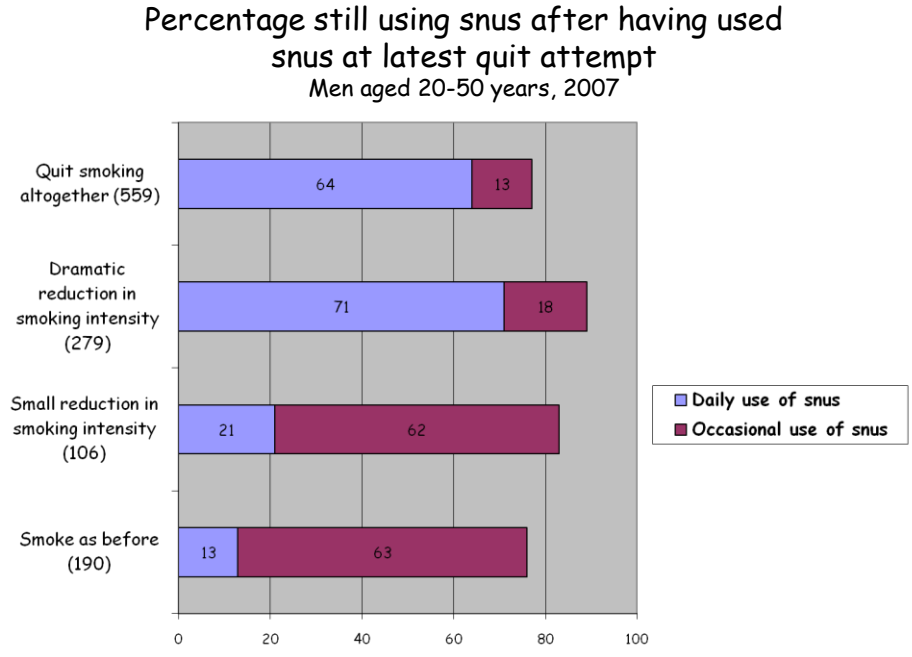
Smoking cessation aids used by Norwegian male ever-smokers 1997-2008. Weighted mean successful and unsuccessful quitters.



[9] As part of a PhD study, SIRUS will examine more closely the barriers that smokers give for use of NRT products at smoking cessation.

Smoking cessation aids used by Norwegian female ever-smokers 1997-2008. Weighted mean successful and unsuccessful quitters.





7.2 What help do health care personnel offer smokers?

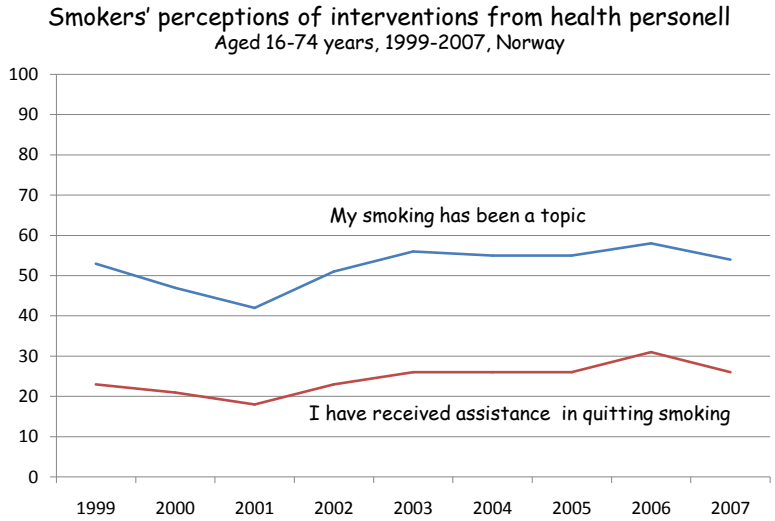
The other strategy for quitting smoking – in addition to medicinal nicotine products – that was highlighted by the five Nordic directors of health, was assistance from health care personnel (Holm et al. 2008). In order for this to be effective: i) health care personnel must be willing to allocate time to intervene to help smokers quit, ii) the interventions must be effective. Is this the fact?

7.2.1 The extent of help from health care personnel

The amount of help that health care personnel provide in Norway has been investigated, for example using self-reported data from general practitioners (Lund et al. 2000, Gallefoss & Drangsholt 2002, Helgason & Lund 2002), hospital doctors (Bakke 2000), dentists (Lund et al. 2002) and health visitors (Lund et al. 2000). Briefly, these studies have clearly shown that there is great potential for increasing the efforts of health care personnel to assist smokers to quit. According to self-reports, only 30 per cent of patients were routinely screened for their smoking habits, and therefore identified if they needed help. The real figure is probably lower, because of selection bias (health care personnel who do not intervene have a lower response rate in studies of this type) and because the answers are influenced by social desirability (exaggerating one's own efforts).

The most important reasons why health care personnel did not intervene was that the effort was felt to be wasted because so few smokers quitted, and the activity was regarded as time consuming (Helgason and Lund 2002). The most recent study was carried out among general practitioners in the spring of 2008, and showed that the efforts made by doctors are still too limited to be expected to have a large effect on smoking cessation rate (to be published).

In addition to self-reports from health care personnel, in several studies smokers have reported whether they mean that they have been given help to quit smoking. The figure below confirms that relatively few smokers in the course of their smoking career have been offered any help from health care personnel, but that help was offered slightly more often in 2007 than in 1999. During this period, the Norwegian Medical Association has repeatedly encouraged its members to help smokers to quit, clinical guidelines for smoking cessation have been published, and the authorities have introduced a fee for doctors for helping patients to quit.



A study carried out in 2007 by Norstat for the pharmaceutical company Pfizer showed that seven out of ten Norwegians had never been asked by their doctor if they smoked, and nine out of ten reported that their doctor had not asked about smoking at the last consultation. Just as many reported that the doctor had not asked about smoking during the last year. Only 8 per cent reported that their doctor had actively helped them with a plan to quit (ANB-NTB 2007).

7.2.2 What effect does help from health care personnel have?

In Cochrane reviews (http://www.cochrane.org/reviews/en/topics/94.html) a series of systematic literature reviews have been published on the effect of interventions from health care personnel on smoking cessation *(physicians, nurses, dental setting, pharmacies, hospitalized patients, individual behavioral counseling, group behavioral therapy, proactive telephone counseling),* and the effect of other types of interventions *(partner support, community support, exercise, incentives/competitions, Quit & Win, mass media, self-help interventions).* In other words, a robust basis has been established for drawing conclusions about the effect of interventions on smoking cessation. Below we present the authors' conclusions from relevant areas, as they are published in Cochrane. These literature reviews show that

interventions from health personnel can help smokers to quit, but that the effect is limited.

Physicians: *Simple advice has a small effect on cessation rates. Assuming an unassisted quit rate of 2 to 3%, a brief advice intervention can increase quitting by a further 1 to 3%. Additional components appear to have only a small effect, though there is a small additional benefit of more intensive interventions compared to very brief interventions.*

Nurses: *The results indicate the potential benefits of smoking cessation advice and/or counselling given by nurses to patients, with reasonable evidence that intervention is effective. The evidence of an effect is weaker when interventions are brief and are provided by nurses whose main role is not health promotion or smoking cessation.*

Dental setting*: The major implications of these findings are for smokeless tobacco users in the dental settings, as we found limited evidence for the effectiveness of similar interventions for cigarette smokers.*

Community Pharmacy Personnel*: The limited number of studies to date suggests that trained community pharmacists, providing a counselling and record keeping support programme for their customers, may have a positive effect on smoking cessation rates. The strength of evidence is limited because only one of the trials showed a statistically significant effect.*

Hospitalized patients*: High intensity behavioural interventions that begin during a hospital stay and include at least one month of supportive contact after discharge promote smoking cessation among hospitalised patients. Interventions of lower intensity or shorter duration have not been shown to be effective in this setting.*

Individual behavioral counseling*: The review looked at trials of counselling by a trained therapist providing one or more face-to-face sessions, separate from medical care. All the trials involved sessions of more than 10 minutes, with most also including further telephone contact for support. The review found that individual counselling could help smokers quit, but there was not enough evidence about whether more intensive counselling was better.*

Group behavioral therapy*: Group therapy is better for helping people stop smoking than self help, and other less intensive interventions. There is not enough evidence to evaluate whether groups are more effective, or cost-effective, than intensive individual counselling.*

> ***Proactive telephone counseling***: *There is evidence of a dose response; one or two brief calls are less likely to provide a measurable benefit. Three or more calls increases the odds of quitting compared to a minimal intervention such as providing standard self-help materials, brief advice, or compared to pharmacotherapy alone.*

So the situation in Norway, and probably also in the other Nordic countries, is that we have a body of health care personnel that, despite encouragement, guidelines and fees, allocate time to smoking cessation only to a limited extent. At the same time, the limited help that is given in the form of counselling and medicinal nicotine products cannot be expected to have large results. In addition, 71 per cent of doctors reported that a barrier is that intervention for smoking cessation is regarded as a waste of time, since so few smokers manage to quit. (Helgason & Lund 2002). The situation is that the authorities have established a series of incentives to motivate smokers to quit, but the assistance offered to smokers to help them quit is limited. The need for harm reduction measures must be seen in the light of this imbalance between motive and assistance.

8 Harm reduction in British and North American tobacco policy

The tobacco epidemic is in its longest and most advanced phase in countries such as England, the USA, Canada and Australia. Cigarette smoking first began to be a widespread phenomenon in these countries, and then spread to other countries. But these English-speaking trend-setting nations have also been innovative within preventive tobacco policy. There is therefore reason to follow closely the discussions that are going on about harm reduction in these countries.

8.1 England

In England, Cancer Research UK (CRUK), the British Heart Foundation and Action on Smoking and Health (ASH) recently published the report: *Beyond smoking kills: protecting children, reducing inequalities* (http://www.ash.org.uk/files/documents/ASH_691.pdf). The report was published in connection with the 10-year anniversary of the White Paper *Smoking Kills*, that marked the start of the British authorities' aggressive preventive tobacco policy. In *Beyond smoking kills,* 44 recommendations were made for preventive measures for the next ten years. Most of these measures are quite traditional, are non-controversial, and are part of most countries' "arsenal of weapons" against tobacco. Most of them have also already been introduced, or are being introduced, in Scandinavia. The report was produced by the leading tobacco experts in England and supported by more than one hundred British health organizations. However, it contains recommendations for harm reduction that representatives for state tobacco prevention in Scandinavia will find radical. Not only do the most benchmarking forces in England recommend harm reduction as the strategy of the future, they also argue that harm reduction will be appropriate for reducing social inequalities in health status.

> *"Smoking prevalence is declining but not fast enough. Too few people successfully quit every year and too many people start smoking. New ways of driving down smoking prevalence are needed. Smokers are addicted to nicotine but are harmed by the tar and toxins in tobacco smoke. It is therefore possible for smokers who are currently unable or unwilling to quit to satisfy their nicotine craving at much lower risk by switching to pure nicotine products (which, like the current medicinal products on the market, contain only nicotine and not other tobacco derivatives). Although these*

products are not 100% safe, they are many orders of magnitude safer than smoking. Given the higher levels of addiction among the most disadvantaged smokers, the promotion of wider access to pure nicotine products as an alternative to smoking is an important means of tackling health inequalities."

Specifically, the benchmarking report contains the following recommendations for British state tobacco policy:

Develop a strategy and an appropriate regulatory structure to improve the acceptability, attractiveness and accessibility of pure nicotine products for use as an alternative to smoking for those smokers who are currently unable or unwilling to quit.

Encourage commercial development of pure nicotine products designed for long-term use as a replacement for smoking.

Develop a communications strategy to counter public misunderstanding of the health impacts of nicotine. This should promote nicotine replacement therapy for quitting and encourage the longer-term use of pure nicotine products as alternatives to tobacco.

Tax pure nicotine products at the lowest rate of VAT.

Evaluate the cost-effectiveness of providing pure nicotine products free on prescription to smokers for as long as they are unable or unwilling to quit.

Increase investment in research into the long-term impacts of nicotine.

The Royal College of Physicians (UK) expressed its views about harm reduction in its report published in 2007: *Harm reduction in nicotine addiction: helping people who can't quit"* (RCP 2007). This prestigious branch of the British Medical Association was very positive to use of harm reduction in the area of tobacco:

"In this report we make the case for harm reduction strategies to protect smokers. We demonstrate that smokers smoke predominantly for nicotine, that nicotine itself is not especially hazardous, and that if nicotine could be provided in a form that is acceptable and effective as a cigarette substitute, millions of lives could be saved"……."Harm reduction is a fundamental component of many aspects of medicine and, indeed, everyday life, yet for some reason effective harm reduction principles have not been applied to tobacco smoking. This report makes the case for radical reform of the way

that nicotine products are regulated and used in society. The ideas we present are controversial, and challenge many current and entrenched views in medicine and public health. They also have the potential to save millions of lives. They deserve serious consideration."(RCP 2007).

8.2 USA

In October 2008, the American Association of Public Health Physicians considered the issue of using the principle of harm reduction in the area of tobacco. The resolution and the report can be found on the web site: http://www.aaphp.org/ Feb07tobaccbill.html.
The Association concluded that application of harm reduction in the area of tobacco can reduce tobacco-related mortality by 50 to 80 per cent over the first ten years and by 90 per cent within 20 years.

> *"It is our perception that the current base of tobacco-related science is more than sufficient to support adding harm reduction as a component of programming intended to reduce tobacco-related illness and death. ... Addition of a ham reduction component could yield a 50% to 80% reduction in tobacco-related illness and death over the first ten years, and likely a reduction of up to 90% within 20 years. These projections are based on the expectation that a significant number of smokers will continue to smoke and the knowledge that risk of death from lung cancer continues for decades after the smoker has stopped smoking".*

In the USA, the resolution from the public health physicians was regarded as a *"landmark event for tobacco harm reduction"*, because it was the first time a professional organization of physicians in the USA had assessed and then come out in favour of harm reduction.

8.3 Canada

However, in Canada, the organization *Physicians for a Smoke-Free Canada* has a different view. In the non-scientific and propagandistic report: *"The snus experience. Lessons from Norway, Sweden and Canada on the public health consequences of widespread oral tobacco use"* (2007), data from Norway, Sweden and other sources were reviewed, and the conclusion was that snus is superfluous in Canada, because, without use of snus, there has been a marked reduction in use of tobacco.

Even though the tobacco control establishment in Canada is still sceptical to snus and the principle of harm reduction, there are also some eminent

individuals within the tobacco control movement who take a positive stance. David Sweanor, health lawyer and participant in Canada's tobacco policy during the last twenty years, in a series of publications has enthusiastically described visions of the effects of harm reduction:

> *"Applying harm reduction principles to public health policies on tobacco/nicotine is more than simply a rational and humane policy. It is more than a pragmatic response to a market that is, anyway, already in the process of undergoing significant changes. It has the potential to lead to one of the greatest public health breakthroughs in human history by fundamentally changing the forecast of a billion cigarette-caused deaths this century"* (Sweanor et al. 2007).

8.4 New Zealand

SmokeLess New Zealand is a benchmarking alliance of health organizations and activists that works to phase out and forbid smoking within ten years. This shall be achieved, for example, by allowing nicotine-dependent people to use snus. The organization, which has been given conditional support from the authorities, justifies its radical recommendation on the grounds of the extreme risk of death associated with cigarette smoking, and with forecasts that show that, with the present rate of reduction in smoking, it will take 70 years before smoking is at a minimum level.

> *"SmokeLess, a new charitable trust, aims for near zero smoking prevalence, by promoting a new deal for smokers. Smokers unwilling or unable to stop smoking, will be able to switch to a nicotine-friendly but smokeless lifestyle, free of lung cancer and emphysema. In addition, gradually reducing the nicotine of cigarettes will make it easier for smokers to switch to smokeless nicotine, or to quit tobacco altogether. With safer choices for smokers in place, fewer will smoke and a law to end sales could put cigarettes out of the reach of children within ten years". http://www.smokeless.org.nz/aims.htm*

8.5 Scotland

In 2007, the organization *Action on Smoking and Health* (ASH) in Scotland published a *'position paper'* with the title: *"Should the EU ban on Snus be Lifted?"*. The answer was no, based on six points: the effect on health of use of snus is not certain, a gateway effect cannot be discounted, it is not certain that use of snus is an effective method for quitting smoking, it is

not correct to use snus as a harm-reducing product as long as there are other, conventional measures for reducing smoking, the existing medicinal nicotine products for quitting smoking have lower potential for causing harm to public health than snus, and to increase the rate of quitting smoking among vulnerable social groups is a more correct strategy.

8.6 European Respiratory Society (ERS)

In October 2005, the ERS Smoking Prevention Committee organized a research seminar: "*Tobacco Smoking: Harm Reduction Strategies*". Among the contributors were the eminent researchers Nigel Gray, Murray Laugesen, Neal L Benowitz and David Balfour. The resolutions from the seminar were:

> *"Harm Reduction is desirable as part of a comprehensive tobacco-control programme.*
> *Nicotine is not the main cause of health problems.*
> *Combustible products cause the most harm.*
> *The status quo should not continue.*
> *Snuff is a lot less harmful than cigarettes.*
> *Snuff also has potential as a smoking cessation aid.*
> *Lifting the EU ban on snuff within a proper regulatory framework needs to be considered.*
> *The playing field for "clean nicotine" should be levelled via deregulation and taxation and pricing measures.*
> *Toxic ingredients should be removed from conventional cigarettes."*
> (Martinet et.al 2006).

9 Harm reduction policy must be made legitimate by the authorities

In order for a harm reduction policy to be successful, it is important – maybe also decisive – that it has the support of the authorities. It seems that it is the snus industry in particular that promotes harm reduction, and this is most unfortunate. There is little reason to believe anything other than that their activities are motivated by commercial interests, and not by a genuine commitment to improving public health. The snus industry exploits the hostile climate to smoking to promote sale of their smoke-free products, and they find arguments from the scientific harm/reduction debate to justify their position. It augers no good that the international cigarette industry are presently buying themselves into the snus industry. There is reason to believe that the cigarette industry wishes to sell snus in addition to – and not instead of – cigarettes. They regard snus as a "bridging product", that can be used in social situations where there are smoking restrictions, to retain smokers as customers (nicotine maintenance policy). In addition, there are several examples that indicate that the snus industry is carrying out innovative product development with a view to recruiting young people of both sexes to use snus.

However, a harm reduction policy made legitimate by the authorities could involve informing people about snus (and other nicotine products with the potential to be used as substitutes for cigarettes, if sale of such products was allowed) as an alternative to cigarettes in specific population groups. With the use of message content, choice of media and social linguistic codes, the authorities could aim their message to the groups of smokers who cannot manage to quit smoking by any other means. Of course, at the same time, the authorities would have to continue to warn against use of snus in naïve populations – population groups with no previous experience of tobacco (for example, young people). To inform smokers who have been unsuccessful in quitting about the relative health hazards of snus in relation to cigarettes, and at the same time to warn young people about the same product, should be a manageable task for qualified information experts (tailored marketing).

In a hypothetical situation in which the authorities in Scandinavia change their opinion, do what they do in drug policy, and support a harm reduction strategy, a series of new challenges would present themselves. Of course, the most important would be to prevent the use of harm-

reduction products in naïve groups. Smokers with a high level of ability to quit without using nicotine substitution products are also not a target group for harm reduction. In addition, it must be decided which products are acceptable harm-reduction products. A system for monitoring the effect of harm reduction at the population level must be established, including studying the effect of harm-reduction products on smoking behaviour.

9.1 Why not allow the transition from cigarettes to snus to take place without the influence of the authorities?

Among Swedish men, the proportion of snus users is now greater than the proportion of smokers. This is also the case among young men in Norway. The use of snus among young women is in an early phase of growth, and smoking seems to be reducing somewhat more slowly – but not much. In Sweden, almost 60 per cent of tobacco is sold as snus. In Norway, sales figures show that the market share of snus has increased from 5 per cent to 25 per cent in less than 15 years, and is now at a level with the market share of roll-your-own tobacco (RYO) (23 per cent). Only ten years ago, RYO was the most popular tobacco product, with a market share of 48 per cent. During the last few years, manufactured cigarettes have had a market share of almost 50 per cent. Thus, in total, the market is shifting to a higher proportion of snus, but cigarettes – by far the most hazardous product – still have three-quarters of the market in Norway. In Denmark, Finland and Iceland nearly all tobacco is consumed as cigarettes.

Everyone – even the most intransigent snus opponents – must accept, even if tacitly, that the observed shift in the tobacco market during the last decades in Norway and Sweden represents a development that has led to improved public health. An apparently comfortable position in the harm-reduction debate would maybe be simply to allow the market, without outside influence, to shift from cigarettes to snus, without trying to speed up this trend by giving smokers information about the relative health risks of snus and cigarettes. In this way, the authorities would avoid the burden of giving positive information about a tobacco product that is "less hazardous than….". This position causes several ethical dilemmas.

First, continued withholding of information about relative health hazards would consolidate widespread misconceptions in the population about the relative risks of the different products. Second, such misconceptions could slow down the transition from consumption of dangerous cigarettes to consumption of much less dangerous snus products. Third, it is ethically defensible not to intervene by providing corrective information about relative health risks when it is highly probable that this intervention would result in a net gain for public health. Continuing to ignore harm reduction in tobacco policy is becoming an increasing ethical problem for the health authorities. As a health agent with certified power to be able to change the conditions for use of tobacco, one should perhaps ask oneself: What is more important – to redeem people from tobacco, or to reduce tobacco-related mortality even if the method involves continued use of a tobacco product?

10 Conclusions

To get people to understand the necessity for a measure that appears to involve changing the expressed aim of tobacco policy – a tobacco-free society – is a challenging task. The task is no easier when the traditional measures for reducing smoking have been successful. Why should we change direction?

However, harm reduction does not involve a *change* in direction for preventive work. Harm reduction should be regarded as an *additional component* to the measures that have already been shown to be effective. On the way to the final aim of a tobacco-free society, harm reduction could be a pragmatic and temporary measure that could clearly save many lives.

Harm reduction is appropriate because of four factors in two pairs.

The first pair of factors is the social gradient in today's smoking pattern, combined with the fact that research has not identified tailor-made measures for the lower social classes. The second pair of factors is the fact that smokers in the remaining group of smokers have additional social and psychological burdens that reduce their ability to quit, combined with the fact that the measures used and the assistance offered today have little effect. Without encouragement to use harm-reducing nicotine products, a large proportion of the remaining smokers will continue to smoke, and will thus have a 50 per cent chance of dying from a tobacco-related disease. With the status quo in the tobacco/nicotine policy that is given legitimacy by the authorities – that is a policy without an active harm-reduction strategy – use of tobacco will maintain and strengthen future social inequalities in health status.

In Scandinavia up until now there has been little willingness to discuss harm reduction in the area of tobacco. The debate has been hampered by dogmatic statements of principle (particularly about snus) that suppress exchange of opinions and reflections about the ethical implications of harm reduction. Interest for – albeit limited – empirical research that can illuminate the theme has been moderate, taking into consideration the potential that harm reduction has for improving public health. Maybe this report can stimulate less biased debate?

In Scandinavia, the tobacco problem is not substantially less serious now than it was in the 1960s. At that time, doctors did not know the extent of the hazards of smoking (Lund 2007), or that cigarettes would be the cause of so many deaths over the next 40 years. We now have knowledge about the extent of the hazards, nearly all conceivable preventive measures have been used, and we can predict future changes in smoking behaviour. In contrast to the doctors in the 1960s, we are now on the brink of a human catastrophe that *we have been warned* will occur if the reduction in smoking does not speed up. To ignore harm reduction as a future strategy in the area of tobacco can be erroneous in this situation. An uncompromising attitude to a tobacco-free society can deny many nicotine-dependent smokers the possibility to survive, which they could have had if the authorities had assumed a more pragmatic attitude to harm reduction.

10.1 Questions for further debate

Some central questions to discuss in future debates on harm reduction are:

i) Should the aim of a tobacco-free society be replaced by the aim to reduce tobacco-related morbidity?
ii) Should the ban on new nicotine products be replaced by regulations to control nicotine products?
iii) Should the Scandinavian authorities be inspired by the recommended harm-reduction policy of health agents in England and the USA, and encourage production of new harm-reducing nicotine products that can compete with cigarettes?
iv) How important is it really to consider who produces nicotine products (the pharmaceutical industry, the tobacco industry or others) when we decide which products shall be regarded as harm reducing?
v) How can we correct smokers' (and others') misconceptions about the relative health risks of use of different nicotine products?
vi) Should the level of tobacco duties and measures to prevent use of tobacco to a larger extent reflect differences in the relative health risks of the different products?

vii) Should the authorities regard harm reduction in the light of the aim to reduce social inequalities in health?
viii) How long should the authorities take a precautionary principle stance in the harm-reduction debate? How much evidence is needed to make them change this stance?

11 Prologue

About half a year before this report was published in English, an almost identical version was published in Norwegian. In Norway, the report received a lot of attention, and stimulated a continuation of the debate on harm reduction, both in the media and in professional circles. The Norwegian Directorate of Health and representatives of the Norwegian Medical Association have some new points of view that can be interpreted as more positive to harm reduction ideology. For example, a director of division in the Norwegian Directorate of Health said to the newspaper Bergens Tidende under the headline "The Norwegian Directorate of Health is willing to consider snus":

> *The Norwegian Directorate of Health says yes to general practitioners, dentists and other health care personnel being able to recommend health-damaging snus to inveterate smokers. Snus is clearly less damaging to health than smoking. If patients have tried other methods without success, we mean that health care personnel can recommend that they use snus instead, says Knut-Inge Klepp, director of division in the Norwegian Directorate of Health. He stresses that before such a recommendation can be made, other nicotine replacement products, and, if appropriate, medicinal nicotine products, must have been tried. Klepp also stresses that such a recommendation must be made directly by health care personnel to the person who needs advice. He is strongly against a general recommendation.*

On the web site of the Norwegian Directorate of Health, a new attitude to use of snus as a harm-reducing product is confirmed:

> *We know that a large proportion of people who smoke have contact with a dentist or a general practitioner, says Klepp. It is important that health care personnel take up the topic of smoking, recommend quitting, and help people who wish to quit. In the first instance they should try established methods such as nicotine chewing gum, nicotine patches or medicinal nicotine products available on prescription. If patients have tried these methods without being successful, the Norwegian Directorate of Health means that health care personnel in individual cases can consider that the patient should try snus instead.*

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