Taking Nicotine out of Tobacco

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'A cigarette is the perfect type of pleasure. It is exquisite and it leaves one unsatisfied. What more can one want.' Oscar Wilde. The Picture of Dorian Gray, 1891.

Thesis submitted in fulfillment of the requirements for the degree of Master of Public Health, University of Auckland; February 2002

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Acknowledgements

Thanks to all the people who agreed to be interviewed.

Thanks to all the people who offered advice and support and special thanks to George Thomson, Marewa Glover, Velma McClellan, Bill Gruar and my supervisors Professor David Thomas and Dr Murray Laugesen.

Thanks to my family for their advice and support.

ABSTRACT

Objective

To determine how acceptable a strategy of significantly reducing nicotine in tobacco to non-addictive levels is to selected groups of New Zealanders. Specifically, to explore how a government mandated de-nicotinisation of tobacco policy might be introduced including the preparation, implementation and the potential impact.

Methodology

Qualitative in-depth interviews with public health experts and smokers with an open-ended semi-structured interview protocol to guide the interview. The sample consisted of thirty-seven subjects drawn from a sample of smokers, ex-smokers, politicians, government officials, academics, a tobacco control advocate and health reporters using a combination of a convenience sampling and the snowballing technique.

Results

A government-mandated de-nicotinisation of tobacco policy would have some support amongst the public but there could be a major backlash from smokers which would make it politically very difficult to proceed. The barriers could be insurmountable in the current political environment but may be acceptable in the future.

Shifting smokers from nicotine to non-addictive cigarettes, with the option of access to alternative nicotine delivery systems (ANDS), would require a combination of consultation with the public and an education / information campaign to explain the policy.

Policymakers would need to ensure they could manage the probable increased negative health impact on current smokers, in the short term, to achieve the potentially significant population health gains in the future. There could also be social problems in the community with some smokers turning to other drugs. The tobacco industry would

actively oppose the introduction of a government-mandated de-nicotinisation of tobacco policy.

The major advantage of a government-mandated de-nicotinisation of tobacco policy would be to prevent addiction and make it easier for smokers to quit smoking. However a disadvantage could be increasing the harm per cigarette caused by compensatory oversmoking during the market-wide mandated de-nicotinisation of tobacco process.

Conclusions

There is not enough consensus or scientific evidence to support the introduction of a government mandated de-nicotinisation of tobacco policy but there is support for New Zealand to contribute to the research effort internationally. There is also support to monitor the situation internationally and contribute to the research effort. If another country or international organisation were to take a lead on government-mandated de-nicotinisation of tobacco, New Zealand could consider developing similar policy.

There is not enough support politically or from the public for de-nicotinisation. However there is support for the government to contribute to the research effort on de-nicotinisation of tobacco, to gradually reduce nicotine and tar levels, to debate and research policy on strictly controlled availability of nicotine and nicotine free cigarettes and the regulation of tobacco and nicotine.

Glossary

Alternative nicotine delivery devices (ANDS)	Nicotine in products other than smoked tobacco.
Clean nicotine	Nicotine in products other than smoked tobacco.
Carbon monoxide (CO)	A highly toxic gas found in tobacco smoke (Blakely & Bates, 1998)
Compensation or compensatory smoking	Adjustment in smoking behaviour to increase nicotine uptake.
De-nicotinised cigarettes	Cigarettes that have had the nicotine reduced to non-addictive levels whether by manufacturer's choice or government regulation.
De-nicotinisation of tobacco	Government mandated market-wide reduction of nicotine in tobacco to non-addictive levels.
Dirty nicotine	Nicotine in smoked tobacco.
DSM-IV	Commonly used criteria to assess for nicotine dependence (Stratton et al, 2001).
FTC (US Federal Trade Commission) measurement	Standard smoking test for determining cigarette yields.
Medicinal nicotine	Nicotine in non tobacco products to aid smoking cessation.
Harm	Harm per cigarette.
Harm reduction or minimisation in tobacco use	Reduction of population harm caused by smoking tobacco.
Nicotine	A highly addictive drug(Henningfield et al, 1998) in tobacco.
Nicotine delivery device (NDD)	Any device that delivers nicotine to the bloodstream. NDDs include: cigarettes, patches, inhalers, aerosol inhalers, gum and highly modified cigarettes that heat rather than burn tobacco (Blakely & Bates, 1998).
Nicotine-free cigarettes	Cigarettes manufactured from tobacco which has been either genetically modified or modified to contain little or no (or very little) nicotine.
Nicotine yield	The nicotine measured in the smoke of a single cigarette using the FTC smoking test (Blakely & Bates, 1998).
Population harm	Harm of the population
Tar	Weight of total p articulate matter minus the nicotine and water (Stratton et al, 200).
Total particulate matter or cigarette smoke condensate	Composite terms for aerosol particles in the smoke (Stratton et al, 2001).

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CHAPTER 1
INTRODUCTION

This thesis investigates the acceptability of the elimination of nicotine from tobacco among decision makers, the tobacco control community and the wider public. It examines and discusses public reaction and support for reducing nicotine to insignificant levels in tobacco including exploration of the policy issues that would enable this process to take place. It evaluates options and determines the impact of nicotine removal.

The first chapter provides a background section that highlights the significant impact smokinghas had on the health of people nationally and internationally. It also discusses addiction and harm reduction in relation to tobacco consumption.

The research was qualitative and involved key informant interviews with smokers, ex-smokers, public health experts, politicians and health reporters. Qualitative techniques were used to analyse the responses. The methodology of the research is described in chapter three and the findings in chapter four.

1.0 Aims of research

1.1 Overall aim

To determine how acceptable the strategy of significantly reducing nicotine in tobacco to non-addictive levels is to New Zealanders.

1.2 Specific objectives

1. To find out the range of views of smokers, ex-smokers and public health experts about significantly reducing nicotine in tobacco.
2. To explore how such a de-nicotinisation of tobacco policy might be introduced including the preparation, implementation and the potential impact.

1.3 Background

The tobacco epidemic has been documented as the *worst man-made global public health tragedy in human history* (Ginzel, 2000). Worldwide, annual mortality rates from tobacco smoking are expected to rise from 3 million to 10 million over the next 35 years (Peto et al., 1994). Although these rates have shown some sign of abating in western countries with lower lung cancer rates in males, the burden of smoking on health is still enormous.

At least a quarter of the adult population still smoke in the OECD countries. Reductions were made in the 1970s and 1980s but most countries have now come to a standstill. These reductions have been made without including harm reduction as a component of theirtobacco control programme. Smoking among young people is generally decreasing very slowly or at least remaining stable in developed countries. Smoking among males in many developing countries is high with the female rate being very low (but increasing as they are being targeted by tobacco companies) (White, 1999).

Tobacco control programmes have mixed effectiveness in the world. Tobacco taxation increases that are known to be effective in decreasing consumption have not been as widespread as they could have been. The United States of America (USA) has not used taxes to reduce tobacco use as in the United Kingdom (UK), Canada, New Zealand and Hong Kong where taxation has been linked to health goals (Heishman et al., 1997). Despite the increased knowledge of the effects of smoking and increased restrictions on smoking in some developed nations, the tobacco industry continues to successfully maintain its overall world market. While sales are declining in developed countries, they are increasing in the developed world.

Health impact and smoking rates

Tobacco smoking has been a major preventable cause of morbidity and premature death in developed countries (Bates, 1992). It kills 4 million people annually and will kill 10 million a year by the 2020s (WHO, 2000). Tobacco use causes the premature death of around half of all long-term users (Sweanor, 1999). An estimated 4,700 people die each year due to smoking in New Zealand (MoH, 2000). The burden of ill health and early

death caused by tobacco consumption is borne particularly by Maori who have smoking rates of more than twice those of non-Maori. Approximately 25% of adults in New Zealand smoke (MoH 2000) which is a similar prevalence rate to most of the OECD countries. Many of these countries have had rates around approximately 25% for some time but some are starting to trend down now. For example, the 2000 rates for Australia were 20%, Sweden 19%, Hong Kong and Singapore in 1998 were 15%. The USA is at 25%. Within the USA, a number of states have much lower rates than the national average, with California, Utah and Massachusetts at 17%, 15% and 14% respectively (Laugesen, 2001c). While the methods for establishing prevalence vary across these nations, the within-country rates of change show reliable trends (Laugesen, 2001a). These reductions have been made without including harm reduction as a component of their tobacco control programme.

The prevalence rate of smoking declined significantly in New Zealand from the mid 1960s from 36% to 26% by 1991 (MoH, 2000) but this decline has not continued with the rate staying at around 25% since 1991. There has also been an increased uptake of smoking among young people in the 1990s which has also occurred in some other developed countries (Scollo, 1997). However, New Zealand smokers do smoke less cigarettes per day than most other OECD countries. They smoke, on average, 12 cigarettes per day (MoH, 2000) compared to 19 cigarettes per day in the USA (CDC, 2000).

Harm Reduction

> *At present there is no agreement in the addictions literature or among practitioners as to the definition of harm reduction* (CC SA, 1996, p. 1)

Many different policy strategies may contribute to harm reduction (Stratton et al., 2001) but strategies that place a priority on reducing the negative consequences of continued use of the drug at least in the short term are harm reducing (CCSA, 1996). It must be remembered however that diminishing harm does not eliminate it (Shatenstein, 1999a).

Harm reduction can be otherwise known as harm minimisation, risk reduction or risk minimisation (CCSA, 1996).

Harm reduction has primarily been associated with illicit drug use (Berridge, 1999) but there is now increasing debate among scientists whether this should be extended to the use of tobacco:

> *'The nicotine in these products is a drug. The products themselves are nothing more than devices for the delivery of that highly addictive drug'* (Zeller, 2000a, p. 4).

Public health experts working in tobacco control have often avoided usingthe term harm minimisation / reduction (Borland, 1997a), as it has generally been associated with illicit drugs. Despite regulatory problems, there are signs health authorities are startingto take harm reduction seriously (Wilson, 2001). Until recently, most of the discussions around harm reduction have been about reducing the chemicals in tobacco smoke not about reducingthe nicotine to non-addictive levels. It is only in the last 5-6years that the discussion has moved to considering whether there may be some merit in significantly reducing levels of nicotine in tobacco.

Harm reduction in tobacco control

The term harm reduction will be used throughout this thesis. It refers to harm reduction in the broader sense of the term encompassing the reduction of the total harm of the population not just reducingthe harm per cigarette to reduce the risk to an individual. Total harm can be expressed as:

Total harm = Harmfulness (per use) x *Intensity (per user)* x *Prevalence (of use)* Harm can be reduced through a decline in any one of the three components individually (Stratton et al., 2001).

Reducing nicotine content in tobacco to non-addictive levels is an untried harm reduction strategy for reducing population harm caused by smoking. The process of nicotine reduction has been the subject of little research and much debate among international

tobacco product regulation experts over the last few years. Thetobacco industry has the technology to manufacture nicotine-free or de-nicotinised cigarettes using three different processes:

- ? De-nicotinisation of tobacco which involves chemically removing the nicotine during the manufacturing process, within a set timeframe. The timeframe could b e overnight or over a period of years.
- ? Growing genetically modified tobacco plants to manufacture into nicotine-free tobacco.
- ? Low-nicotine tobacco l eaf p lants to manufacture into nicotine-free tobacco.

Whilst these cigarettes may not be totally nicotine-free, they would be *virtually free of nicotine* and would be below the threshold of addiction. De-nicotinisation of tobacco is the process that will be explored in this thesis.

De-nicotinisation of tobacco has been promoted by the American Medical Association (AM A) (Henningfield et al., 1998). There are other harm reduction approaches which do not alter tobacco products and / or use pharmacological agents, for example, behavioural methods and current tobacco control policies. All these strategies are best employed as part of a comprehensive tobacco control programme aimed at reducing smoking (Stratton et al., 2001). Virtually eliminating nicotine is a harm reduction strategy, even though nicotine as one of the less hazardous constituents of the tobacco is being reduced and the most harmful constituents remain. It is the combination of the harmful constituents with the addictive constituent nicotine which ensures smoking continues long enough to cause cancer, emphysema and other tobacco-related diseases. The aim of de-nicotinisation of tobacco is to protect:

- ? Current smokers, by help ing them to quit smoking
- ? Ex-smokers, by preventing them from becoming addicted if they relapse and have an occasional cigarette
- ? Young never smokers, by preventing them from becoming addicted if they decide to experiment with smoking, and to ensure they do not continue smoking.

It is uncertain whether smokers would quit during the process of de-nicotinisation or wait until the nicotine levels were below the threshold of addiction which is estimated to be at around 0.17 mg of nicotine per cigarette (Henningfield et al., 1998). Similarly, it is uncertain exactly when young smokers would actually discontinue their smoking, either through a lack of interest and / or a lack of addiction.

This thesis reports on the research of a proposed harm reduction plan and the acceptability of that plan among key stakeholders. The intervention would involve the introduction of a tobacco control policy that aims to reduce the consumption of tobacco, by eventually banning the sale of all tobacco products containing an addictive level of nicotine. A product is considered harm-reducing, if it lowers total tobacco-related mortality and morbidity, even though the use of that product may involve continued exposure to tobacco-related toxins (Stratton et al., 2001).

Drug addiction or drug dependence

The terms *drug addiction* and *drug dependence* are considered to be synonymous by the U.S. Surgeon General, World Health Organisation (WHO), American Py schological Association and the American Psychiatric Association (Heishman et al., 1997). The primary criteria for drug dependence include:

> *'Highly controlled or compulsive use of a drug, psychoactive effects from the drug, and drug-reinforced behavior* (USDHHS, 1988, p. 7)'

As shown in Table 1 a number of criteria have been established to define addiction clinically (Shatenstein, 1999a). Both the Diagnostic Scientific Manual Version IV (DSM IV) and the World Health Organisation International Diagnostic Code(IDC) are the most commonly used criterieato assess for nicotine dependence (Stratton et al., 2001).

Table 1.1: Addiction assessment

Criteria for Substance Dependence from DSMIV	
DSM-IV	**IDC-10**
A maladaptive pattern of substance use, leadingto clinically significant impairment or distress, as manifest by three (or more) of the following, occurring at any time in the same 12-month period	
□ Tolerance - need increased amounts of substance to achieve desired effect, or diminished effect with continued use or same amount □ Withdrawal □ Substance often taken in larger amounts or over a longer period than intended □ Persistent or unsuccessful efforts to cut down or control substance use □ Great deal of time spent in activities necessary to obtain the substance or recover from its effects □ Important social, occupational, or recreational activities given up or reduced because of substance use □ Substance use continued despite knowledge of having a persistent or recurrent physical or psychological problem likely to have been caused or exacerbated by the substance	□ Increased tolerance □ Sometimes, phy sical withdrawal □ A strong desire to take the drug □ Difficulty controlling use □ Higher priority given to drug use than to other activities and obligations □ Persistinguse despite harmful consequences

Source: (APA,1994)

All of the DSM-IV and IDC criteria are true for nicotine except givingup important activities which are usually associated with intoxication (Shatenstein, 1999a), as with alcohol use. Although many smokers will go outside for a cigarette repeatedly in work time. Not all drugs that are addictive meet each criteria.

In 1988, the US Surgeon General reported that cigarettes are addictive and nicotine is an addictive substance. This was reaffirmed by the American Society of Addiction Medicine (ASAM) , the organisation that represents addiction concerns at the AM A.

1.4 The present situation

When this thesis was initiated cigarettes de-nicotinised during manufacture were the only type of non-addictive cigarettes that had been introduced to the market. The qualitative research was undertaken on that basis. However, new cigarettes by Vector Tobacco are being developed in which the tobacco plant is genetically modified. They are reported as being virtually nicotine-free. According to Vector Tobacco from Durham in North Carolina the tobacco, Omni Nicotine Free will produce no nicotine and also have reduced carcinogens (ENN, 2001). Vector is planning to introduce this cigarette to the market in the USA early in 2002 (ENN, 2001). They could well be on the market in New Zealand soon after that.

The questionnaires designed for interviewing key informants were based on the information to hand at that time. The findings came from the analysis of the interviews, which related only to the use of de-nicotinised cigarettes and alternative nicotine delivery systems (ANDS). The Vector cigarettes were not considered as part of this research. Whilst the end product is similar, the reduction of nicotine in cigarettes happens over a period of time in de-nicotinised cigarettes and Vector nicotine-free cigarettes are manufactured as nicotine-free. A mandated market-wide policy of nicotine reduction in tobacco could be sudden or gradual. It could happen overnight or it could take years. Exploringthe de-nicotinisation process is as much a part of the research topic as examiningthe possible end result of de-nicotinised tobacco products. In contrast, nicotine-free cigarettes would come onto the market immediately as nicotine-free cigarettes and would not necessarily require any new public policy under the current law.

There is still a lack of consensus internationally among public health experts about whether nicotine in tobacco should be reduced to non-addictive levels (Zeller, 2000a). While the experts debate and continue to research the benefits of reducing nicotine to non-addictive levels in cigarette tobacco, Vector is planning to market its nicotine-free cigarettes.

Concern about nicotine-free and reduced carcinogen cigarettes coming to New Zealand before the Ministry of Health has strengthened the regulatory systems has prompted a discussion document to be prepared from the non-government organisation (NGO) sector (Laugesen, 2001b). Without a strong regulatory system the cigarettes could be marketed as *safe cigarettes.*

1.5 Treaty of Waitangi

The Government regards the Treaty of Waitangi as the founding document of New Zealand (Durie, 1994). It is in effect a type of moral and political contract between the Crown and Maori, although it has also entered the mainstream of New Zealand law in the last 15 years.

There has in the past been a failure to incorporate or acknowledge the Maori paradigm when research has been undertaken with Maori. The current practice is to assume the Maori paradigm is valid and legitimate and incorporate it into research using the Treaty of Waitangi as a guiding document incorporating the principles of partnership, participation and protection.

Maori should be able to enjoy the same health status as non-Maori. The Crown's objective is there should be no differences between the health status of Maori and non-Maori (Durie, 2000).

In considering the expected implications and impact of a policy of denicotinisation of tobacco, directly or indirectly on the health status of Maori, services provided will need to be accessible, appropriate, affordable and acceptable to ensure the best health outcomes. Many of these services will need to be, and some already are provided by Maori, for Maori.

If the introduction of a de-nicotinisation of tobacco policy was likely to have a positive impact on the health of New Zealanders, Maori would have the most to gain as they

smoke twice as much as non-Maori. On the other hand if there was likely to be a negative impact Maori would have a greater net health loss compared to non-Maori.

1.6 Summary

This research into the public acceptability of a de-nicotinisation of tobacco policy is about a hypothetical, but plausible situation. No country in the world has introduced a public health policy which over a period of time phases out nicotine cigarettes, leaving only non-addictive cigarettes available on the market. The literature reviewed above reveals a lack of consensus on which harm reduction strategies in tobacco control should be pursued. Part of the reason for this is, there are still questions about the science involved in reducingthe harm caused by smoking (Zeller, 2000a).

By current international standards New Zealand has a fairly comprehensive tobacco control programme and it has the makings of a very supportive environment for smokers to be weaned off nicotine in tobacco. Many public indoor environments and workplaces are totally smokefree and a national quitline with subsidised nicotine replacement therapy (NRT) provides easy access to treatment for smoking cessation. Societal and political support is strong for other tobacco control policies that have already been adopted, although, smokers whilst supportive of other policies may not necessarily approve of a de-nicotinisation of tobacco policy. New Zealand has the advantage of being an island nation and therefore smuggling of nicotine cigarettes would be more difficult. Could the present national tobacco control programme provide the basis for taking *radical steps* to ensure public health gains, by reducing nicotine in tobacco to non-addictive levels and would such a policy be feasible? This thesis will describe, explain and make recommendations for developing an effective harm reduction strategy in the future.

CHAPTER 2
LITERATURE REVIEW

This chapter describes the issues around harm reduction as a strategy and more specifically the elimination of nicotine from tobacco. The literature review provides the scientific evidence that is drivingthe move towards the inclusion of harm reduction strategies as part of comprehensive tobacco control programmes. It specifically reviews literature on the elimination of nicotine from tobacco and the acceptability of non-addictive tobacco products among consumers and policymakers.

2.1 Overview

In the process of reviewing literature on harm reduction this chapter will describe nicotine addiction and the difficulty breaking that addiction. Issues around addiction to nicotine and shifting that addiction from nicotine in smoked tobacco to alternative nicotine delivery systems (ANDS) are discussed. Smokers are not likely to accept de-nicotinised tobacco very easily. They would probably compensate for the lack of nicotine by oversmoking.

Regulation of nicotine is a key issue in controlling the process of eliminating nicotine from tobacco but there are significant problems in regulating nicotine in tobacco and alternative nicotine products. Thepublic health implications of implementing a de-nicotinisation of tobacco policy are significant with enormous public health gains to be made but also potential population harm risks which need to be considered.

The unintended consequences, for example, an increased black market and smokers accessing nicotine cigarettes are a potential concern. The international position on de-nicotinisation of tobacco as a policy is still unresolved with research and debate continuing. Finally, the unanswered questions that remain are discussed.

2.2 Search procedures

In the literature review the key words nicotine, acceptability, regulation, eliminating, reduction, cigarettes, policy, delivery-devices, alternative nicotine devices, compensation were combined in undertaking the searches of three relevant bibliographic computerised databases Medline, Psychlit and CINHAL since 1995. Globalink, the Society for Research on Nicotine and Tobacco and the Tobacco Control Network listserves were perused from time to time duringthe period 2000-2001 to check for new developments in population harm reduction and potential reduced-exposure products (PREPs). Key documents on nicotine were reviewed as part of the analysis of policy options and to help in the consideration of the implications of reducing nicotine to non-addictive levels in tobacco.

2.3 Harm reduction

Harm reduction in tobacco use has the potential to significantly benefit public health but harm reducing products must lower total tobacco caused morbidity and mortality (Kozlowski et al., 2001).

History of 'tobacco controlled' harm reduction products

The health community has realised since the 1950s that lung cancer was prevalent among smokers (Stratton et al., 2001), yet reducing the harmfulness of tobacco has been left largely in the hands of the tobacco industry. The tobacco industry realised that concerns about the ill-health effects of smoking needed to be addressed. The industry has been researching and develop ing *less hazardous* products in an effort to retain and expand their market. However, to date they have not been able to develop a *less harmful* cigarette (Stratton et al., 2001).

The tobacco industry cannot be relied upon to come up with a *less hazardous* product as they are in the business of making a profit. They design their products to be more appealing, have made no real effort to reduce the harmfulness, have been fraudulent in their promotion of *light* and *mild* cigarettes, failed to adequately inform consumers of the content or to help them quit, have actively marketed cigarettes, targeted young people

(Chapman, 2001) and promulgated lies (Borland, 2001). The development of *less hazardous* products (smoked or alternative nicotine products) needs to be controlled and regulated by the government to ensure *less hazardous* tobacco products that are produced by the tobacco industry are not promoted as *safer* products to smoke. Table 2.1 gives examples of two tobacco products that have been developed by the tobacco industry in response to public concern about the effect of smoking on health. The third product is nicotine replacement therapy (NRT) which is used as a cessation aid and has not been developed for long term continued use.

Table 2.1: Three Interventions in Tobacco Use with Harm Reduction Rationales

Product	**Presumed or Declared Mechanism**	**Effect on Prevalence**	**Harms to Others**	**Effect on Intensity of Use**	**Potential Threats to Reducing Harm**
'Light' & filter Cigarettes	Less dangerous product	Increased cigarette consumption	Increased	Increase	Adaptive behaviour negates technology/raises prevalence
Modified tobacco - reduced yield of selected toxicants	Less dangerous product	Increased cigarette consumption	Increased	Increase	Exposure reductions not realised/prevalence rises too much
Nicotine Replacement Therapy	Substitute product	Decreased smoking?	Reduced	Reduce	Prolongs smoking careers/incomplete compliance

Source: (Stratton et al.,2001)

Filtered cigarettes were developed in the 1950s by the tobacco industry with a declared concern for smokers' health. Tobacco companies from the United States of America (USA) promoted the new cigarettes as a *scientific breakthrough.* They advertised them as *safer cigarettes* which reduced the tar and nicotine intake when consumed .

In 1962, the Royal College of Physicians reported the first instance of a doctor-led attempt at harm reduction. Differential taxes on tobacco products were suggested so

smokers would shift to safer forms of smoking, such as pipe and cigar smoking (Berridge, 1999). There is no evidence this actually occurred but harm reduction remained a theoretical strategy through the 1970s in Britain.

Low-yield cigarettes followed on from filtered cigarettes. These products were lower in tar, nicotine and carbon monoxide (CO) as measured by the US Federal Trade Commission (FTC) test (Stratton et al., 2001). However, the expected health benefit impact of theseproducts has not happened mainly because nicotine intake is affected by factors not accounted for usingthe FTC method of testing. Consumers have been misled on the relative danger of different tobacco products (Jarvis & Bates, 1999b). They have been provided with information that would only be accurate if the smoker smoked in the same way the machine smokes. The tobacco industry have been clever in the way they have designed cigarettes so the smoker is likely to consume more nicotine and tar for any one or all the reasons below:

- Filter vents which are not blocked by the FTC machine will often be blocked by the smoker when smoking (Shopland, 2000).
- Specially blended tobacco is used to increase the nicotine concentration (USDHHS, 1996).
- The porosity of paper will increase the oxygen and dilution of nicotine and tar in the puff volume thereby giving a low nicotine and tar reading. The smoker cannot correct for this unless he / she closes his / her fist around it as some (a few) may do (Laugesen, 2001a).
- Accelerants added to prolong burn time.
- Length of overwrap .

More recently, the tobacco industry has developed products which have been declared to have less carcinogens or deliver nicotine with less combustion. R.J.Reynolds (an American tobacco company) introduced NOW to the market in 1975. NOW had lower tar and nicotine (Stratton et al., 2001). This was followed by Premier cigarettes in 1988 (Wilson, 2001) which have since been taken off the market (Zeller, 2000a) because smokers did not like the taste (Wilson, 2001).

A few years later, the Eclipse cigarette came onto the market (Slade & Henningfield, 1996) and is currently being test-marketed. This product consists of atube of tobacco with a heat source at one end, most of the tobacco does not burn and according to R J Reynolds the smoke contains lower levels of 14 known or suspected carcinogens than from other nicotine cigarettes (Wilson, 2001).

Nicotine-free cigarettes were introduced onto the market in the 1980s in the form of Merit De-Nic, Benson & Hedges De-Nic and Next (Henningfield et al.,1998) manufactured by Philip Morris (Butschky et al., 1995) which were not popular with consumers. Next cigarettes failed to provide the *taste* (nicotine) that smokers needed and could not compete with the demand for *richer* alternatives (Shatenstein, 1999b), like Marlboro. They were rated as less satisfying than the smoker's own brand (Gross et al., 1997).

The Omni Nicotine Free cigarettes coming onto the market in the USA this year are not expected to gain market share (Laugesen, 2001 e), though they may be popular with intending quitters who sincerely wish to taper down their nicotine intake. However, it would be different if they were not competing against nicotine cigarettes. These products, in combination with ANDS, including medicinal nicotine, may in the future be considered harm reducing products (Stratton et al., 2001) with the aim of reducing population harm. Although, in the absence of testing methods being applied to new tobacco products (novel, reduced-risk products) a group of'international experts'[1] are not advocatingthe combination of smokingand using medicinal nicotine, at the present time. They are recommending medicinal nicotine as an alternative form of nicotine for smokers who cannot or will not stop using nicotine in cigarettes (Kozlowski et al., 2001).

Some potential reduced-exposure products (PREPs) are now on the market (see Table 2.2) and more are expected to come onto the market as pharmaceutical and tobacco industries compete to deliver less hazardous products.

'international experts' - refers to renowned international tobacco product regulatory experts

Table 2.2: Potential Reduced-exposure Products (PREPs)

Category	Descriptors	Examples
Modified tobacco	Reduced yield of selected toxicants	Advance, low-nitrosamine tobacco cigarettes, Snus (smokeless tobacco), reduced nitrosamine smokeless tobacco
Cigarette-like products (whether containing tobacco or not)	Less combustion than cigarettes	Eclipse Accord
Pharmaceutical products (whether containing nicotine or not)	Nicotine Replacement Antidepressants Other Medications	Nicotine gum, patches, inhaler, nasal spray Buproprion SR, nortriptyline Nicotine antagonists, clonidine

Source: (Strattonetal., 2001)

Taking control from the tobacco industry

Since the early 1980s some scientists have been predicting that the fall of the prevalence rates of smoking in some countries would begin to slow as a *hard core* of smokers remained addicted to nicotine (Raw, 1997). It has been suggested that the smokers who continue to smoke are heavily addicted to nicotine and cannot quit, despite health protection and promotion programmes which have restricted their access to smoking and encouraged them to quit smoking.

Many public health experts do not accept this theory. It appears to be contradicted by falls of smoking rates to under 15% in parts of California (Orange County 13%) (CDC, 2000). It also appears to be based on a narrow bio-medical or addiction model, and not take social factors into consideration. In New Zealand, Maori with a 50% prevalence rate of smoking and non-Maori with a 25% prevalence rate have the same percentage of those who need a cigarette within thirty minutes of waking. Similarly for blue and white collar differences in prevalence rates of smoking (Laugesen, 2001a).

However, the prevalence rate of smoking remains stubbornly at 25% in New Zealand, as with many other developed countries. The 1990s started with a rate of approx. 28% and were down to 25% by 1998, with a slight increase in 1999 and back to 25% by the year 2000. There is an ongoing group of young people taking up smoking and becoming

addicted to nicotine soon after entering the market, which makes it difficult to reduce the prevalence rate of smoking.

It was against this background in 1996, that the Forty-ninth World Health Assembly (WHA) adopted a Resolution which called upon the Director-General of the World Health Organisation (WHO) to initiate the development of an international Framework Convention for Tobacco Control (FCTC) (Bates, 1992). The regulation of tar and nicotine were identified as a necessary component of the FCTC (FCA, 2001).

In the same year, theMinnesota delegation of the American Medical Association (AMA) proposed that the AMA develop and support legislation that would require the nicotine content in cigarettes to be reduced annually until tobacco products were nicotine-free. They anticipated this would take sixyears (Henningfield et al., 1998). This was a new and radical proposal which was endorsed by the British Medical Association (BMA) and the International Union against Cancer (UICC) (Douglas, 1998). The UICC proposed gradually eliminating nicotine worldwide. To date, there has been very little action except for further discussion at an international level (Borland, 2000).

However, the proposal also has its critics (Jarvis & Bates, 1999a; Las Vegas Review, 1997; Shatenstein, 1999a). The main counter-arguments are about the denial of pleasure to smokers (Shatenstein, 1999a) including:

- ? the cigarettes will not be acceptable to smokers,
- ? the source of harm is in the tar not the nicotine, and
- ? the aspect of prohibition (Las Vegas Review, 1997).

Other arguments were that:

- ? compensatory smoking would cause more harm to the individual smoker,
- ? more people may be encouraged into the cigarette market,
- ? smokers may reduce rather than quit smoking and
- ? there would be an increased black market.

In New Zealand, this strategy has not been vigorously debated. However, by January 1998, theMinistry of Health had contracted the Institute of Environmental Science and Research Ltd (ESR) to prepare a report (Blakely & Bates, 1998) on *'Nicotine and Tar in Cigarette Tobacco, A Literature review to Inform Policy Development'.* The aim of this report was to review the international scientific literature on the behavioural and health effects associated with nicotine and tar and to determine possible options for controlling nicotine and tar levels in tobacco. This was followed up in September 1998 with another report from the ESR (Bates, 1992) on the *'Control of nicotine and tar in tobacco products: Policies of other jurisdictions'.* The ESR in New Zealand are measured in their support for de-nicotinisation of tobacco but do support reducing exposure to tobacco toxins for those who are unable or unwilling to stop smoking and a gradual reduction in nicotine (Blakely & Bates, 1998). TheMinistry of Health has since failed to pursue the issue. It has not called for public discussion or made any other moves to ensure further development of the recommendations within New Zealand.

Today, the international public health experts are still lacking consensus on whether the focus should be on reducing toxins in the tobacco or tobacco smoke, or reducing nicotine to non-addictive levels (Zeller, 2000a). Some maintain the focus should be on both policies. Whatever process is used to reach the same goal of significantly reducing the total harm caused by tobacco use, more research is needed before either policy can be pursued on a wider scale.

Harm reduction in Tobacco Use

There are three methods of reducing the total harm of tobacco use:

- The reduction of tar in tobacco would make the product less hazardous for the smoker who continues smoking or new smokers coming into the market.
- The reduction of nicotine in tobacco would make the product non-addictive and it would be easier for smokers to quit smoking (Blakely & Bates, 1998; Zeller, 2000a) and new smokers coming into the market would not get addicted to nicotine in tobacco.
- The reduction of both the nicotine and tar in tobacco.

These are all viable possibilities that could significantly reduce health problems which result from smoking (Pinney, 1995), although smoking would still be an option. The reduced nicotine option would probably see less people smoking less cigarettes and the reduced tar option would probably see the same number of people smoking but the cigarettes would be slightly less hazardous. Some public health experts consider it would be worthwhile to work on both strategies at the same time (Zeller, 2000a) and there are others who do not support or are wary of any harm reduction strategies as a method of controlling tobacco (Borland, 1997a). Nicotine and tobacco are potentially more dangerous than illicit drugs which could be the reason why those working in tobacco control wish to eliminate use rather than to reduce harm per cigarette (Berridge, 1999). With illicit drugs, the approach has generally been to increase legal access, whereas a harm minimisation approach to tobacco needs to be directed towards reduced access and reduced opportunities to use (Borland & Scollo, 1999).

Maximising or minimising nicotine levels are also part of the debate (Russell, 2001). Minimising nicotine levels is designed to prevent the development of addiction to nicotine whereas maximising nicotine is designed to reduce the consumption of tobacco and therefore the total harm caused by smoking. It is difficult to assess which option would have the best health outcome.

In many ways, it could be said nicotine levels in New Zealand cigarettes are maximised as they are generally higher than most other countries. The rate of consumption is low but that is probably because of the high taxation on tobacco and smokefree environment legislation rather than the high nicotine levels. Nicotine yields have actually reduced reasonably significantly over the last 30 years or so but New Zealand is comparatively high compared to other countries in the OECD. New Zealand smokers do smoke fewer cigarettes than smokers from the USA (CDC, 2000; MoH, 2000), therefore, it could be argued New Zealand smokers are exposed to less overall harm than smokers in the USA. This theory is supported by lower lung cancer rates in New Zealand (Peto et al., 1994).

A maximising nicotine levels approach which has been suggested, but not seriously considered, is elevating the free-base nicotine content of cigarette smoke. This could result in smokers being satisfied with smoking fewer cigarettes, which would result in a reduction of the harm caused by smoking (Fowles, 2001).

Most of the health damage caused by smoking comes from the non nicotine constituents (Borland, 2000), for example, the tar (the weight of the total particulate matter minus the nicotine and water, (Stratton et al., 2001a) and the gas including CO. *'Tobaccoproducts are a very dirty delivery device'* (Sweanor, 1996, p .1) for nicotine. Proponents for reducingtar in tobacco believe that makingthe product *less hazardous* is the approach that should be taken (Bates, 2000). Many smokers fail to stop smoking and it is important for those that do continue longterm, that a *safer* product is developed (Russell, 2001). Proponents of eliminating the nicotine from tobacco argue that it is better to remove the nicotine from tobacco, as consumption would be significantly reduced (Zeller, 2000a) because smokers would smoke fewer cigarettes and therefore there would be a significant reduction in population harm.

There have been very few studies using experimental cigarettes with low tar to nicotine ratios (Russell, 2001). The dual strategy of reduced tar and nicotine has some support and could be considered as a way forward. This is straightforward down to 0.9 mg of nicotine machine yield, but below that yield compensatory smoking is likely to increase (Laugesen, 2001a). However compensatory smoking in many cases may only be temporary.

The tobacco industry believes that if the nicotine was reduced to non-addictive levels in cigarette tobacco, smokers would not continue to smoke. (Douglas, 1998). There appear to be many unanswered questions about the effectiveness of any of the harm reduction approaches and particularly de-nicotinisation of tobacco. However a search of tobacco documents consistently uncovered statements from tobacco executives, which allude to their concern about the removal of nicotine from tobacco. They are in no doubt it would be the *death knell* of the industry (Hurt & Robertson, 1998). Given tobacco control

advocates often refer to the *"scream test"* (the depth of response from the industry), as being an indicator of the likely success of potential policy, it is somewhat puzzling de-nicotinisation of tobacco does not enjoy a higher level of support. Whilst the *"scream test"* is not evidence-based it is considered a rough indicator, as the tobacco industry know their customers better than anyone. In this case, members of the international public health community are not placing much significance on the statements by the tobacco industry on the removal of nicotine from tobacco.

There are several examples of the tobacco industry's concern, that if nicotine were removed or significantly lowered in tobacco, their business would be in trouble. Claude E. Teague of RJ Reynolds (a USA tobacco company) said in a memorandum in 1972:

> *'and, if we meekly accept the allegations of our critics and move toward reduction or elimination of nicotine from our products, then we shall eventually liquidate our business'.* Claude E. Teague (quoted in Hurt & Robertson, 1998, p. 1175)

The quote below from a British American Tobacco (BAT) executive in 1959 fits today's agenda of harm reduction in tobacco use:

> *'To reduce the nicotine per cigarette as much as possible and thus satisfy the trend of consumer demand... might end in destroying the nicotine habit in a large number of consumers and prevent it ever being acquired by new smokers.'* (quoted inLeavell, 1999, p. 433)

Clearly it is a tobacco industry priority to maintain reasonable levels or bioav ail ability of nicotine in tobacco and it has been for some time. Twenty years later nothing had changed:

> ' *Taking a long term view, there is a danger in the current trend of lower and lower (nicotine) deliveries - i.e. the smoker will be weaned away from the habit.'* Dr S.J. Green, Senior British American Tobacco Scientist 1976 (quoted in Lewan 1998, p. 318)

The tobacco industry have even added ammonia to tobacco to increase the nicotine *kick* to the smoker, as evidenced by a quote in an undated (estimated 1980) R.J. Reynolds tobacco document:

> *'Ammoniatedflue cured tobacco ...product characteristics: milder smooth taste; higher smoke pH; cleaner taste with more free nicotine; stronger physiological impact with less harshness.'* (Leavell, 1999, p. 434)

A 1990 R.J. Reynolds tobacco document showed the tobacco industry are continuing their search for *the perfect cigarette* (keeps the smoker hooked but is safe to smoke) by exploring way s to increase nicotine in low tar cigarettes:

> *'Review the use of organic acids and nicotine salts in tobacco burning cigarettes, and recent attempts to develop an ultra low 'tar' cigarette with enhanced nicotine yield'* (Leavell, 1999, p. 434)

2.4 Nicotine addiction

Nicotine and related alkaloids in tobacco are the primary addictive substances in tobacco (Fowles, 2001). Nicotine is the substance in tobacco that ensures it is addictive. Other factors or constituents can enhance or influence the addictiveness of tobacco but without nicotine cigarettes cannot be addictive.

Table 2.3: Twenty alkaloids found in various Nicotiana tobacco species

N-nitrosonornicotine	Anatabine
Nicotyrine	Anabasine
Nornicotyrine	Anabaseine
Metanicotine	Iso-Nicoteine
Nicotimine	Nicotoine
Nicotine N-oxide	Nicotelline
Cotinine	Nornicotine
6'-Oxoanab asine	N-methy lanatabine
Pseudooxy nicotine	N-methylanabasine

Source: (Fowles, 2001)

The criteria for tobacco-delivered nicotine addiction is threefold: daily smoking, difficulty in not smoking daily and withdrawal symptoms (Benowitz & Henningfield,

1994). Addiction can occur within a matter of day s following the uptake of smoking (Fowles, 2001).

In 1988, the US Surgeon General reported that cigarettes were addictive and nicotine is an addictive substance. Excerpts from the tobacco industry which support the Surgeon General's stance include:

> ' *There is no doubt that nicotine plays a large part in the action of smoking for many smokers. It may be useful, therefore, to look at the tobacco industry as if for a large part its business is the administration of nicotine (in the clinical sense)'* (Kessler, 1994a, p. 368).

The tobacco industry has a vested interest in maintaining smokers and recruiting new smokers. Internal documents, consistently reveal their concern about regulation of nicotine and determination to maintain nicotine cigarettes on the market. The quote below was found in aRJ Reynolds document dated 14 April 1972:

> *'Without nicotine..there would be no smoking...No one has ever become a cigarette smoker by smoking cigarettes without nicotine... Think of the cigarette pack as a storage container for a day's supply of nicotine... Think of the cigarette as a dispenser for a close unit of nicotine... Think of a puff of smoke as the vehicle of nicotine... Smoke is beyond question the most optimised vehicle of nicotine and the cigarette the most optimised dispenser of smoke.' 'We are in the business of selling nicotine, an addictive drug effective in the release of stress mechanisms.'* (Douglas, 1998, p.216).

In 1994, the Chief Executives from the major USA tobacco companies denied on oath that nicotine was addictive. However, Philip Morris and BAT are now admitting that smoking is addictive (Zeller, 2000a).

The role of nicotine in tobacco is to maintain addiction (Foulds& Ghodse, 1995). Usually this addiction begins in adolescence. Young people give little or no thought to the problem of addiction (Slovic, 2001) and underestimate the addictive nature of tobacco

(Benowitz & Henningfield, 1994; Hogan, 2000). Once smokers are addicted to the nicotine in tobacco their smoking will be largely motivated by the desire for nicotine (Foulds & Ghodse, 1995) and many of them will be smoking against their will. They will no longer be able to smoke cigarettes out of choice (West, 1995). They will smoke because they are addicted to nicotine (Britton et al., 2000). As a result of this nicotine addiction there is a 40 percent probability of premature death from illness caused by smoking cigarettes (Benowitz & Henningfield, 1994). One in two smokers will die from smoking if they persist in smoking (Peto et al., 1994).

Difficulty breaking the addiction to nicotine in tobacco

It is extremely hard for smokers to quit smoking as nicotine dependence is a barrier to smoking cessation (Hughes, 1995). There is some debate about the actual percentage of smokers who manage to quit but the range of estimations is between 2% (Jimenez-Ruiz et al., 1998) and 20% (Hebert, 2000) for smokers who are still not smoking after one year. Only about half of the smokers who have ever smoked can quit during their lifetime (Jimenez-Ruiz et al., 1998). The primary reason it is so difficult, is that the vast majority are addicted to nicotine (Ananthaswamy, 2000). For smokers wishing to quit it may take from days to weeks to feel normal without nicotine (Heishman et al., 1997). When smokers experience nicotine withdrawal, they can display a number of symptoms including: dysphoric or depressed mood, insomnia, irritability, frustration or anger, anxiety, difficulty in concentrating, restlessness, decreased heart rate and increased appetite or weight gain (Henningfield et al., 2000). Potential quitters need both the desire to quit and the ability to overcome dependence (Kottke & Solberg, 1995) which can be extremely difficult.

Nicotine is as addictive as heroin (Moxham, 2000). The traditional theory of addiction is:

> *'addiction comes when repeated exposure to a chemical weakens its effect, so that a person needs to take more and more of the drug to get a 'hit''* (Ananthaswamy, 2000, p.349).

However, a more recent theory has been developed by Ian Stolerman of the Institue of Psychiatry at Kings College:

> *'repeated exposure increases the user's sensitivity to a drug. And this is what makes the experience more and more pleasurable - and therefore harder to give up'* Ian Stolerman (quoted in Ananthaswamy, 2000, p. 349).

The debate over whether nicotine is addictive or not is all but over among academicians and clinicians, who agree, that nicotine is addictive (West, 1995). However, there are still some dissenting voices. A small number of scientists do not agree nicotine is addictive because it does not result in behavioural intoxication of the smoker but believe smokers remain smoking because it is a pleasurable activity that reinforces the habit (Pritchard & Robinson, 1996). However, there appears to be almost universal agreement among most other scientists and public health experts that nicotine is addictive.

Addiction to nicotine not tobacco

Nicotine addiction is the central problem in cessation efforts (Moxham, 2000). If smokers are having difficulty breakingthe addiction to nicotine in cigarettes, then another solution is to continue to take nicotine through a cleaner delivery device. In the past,NRT has been promoted as an effective cessation aid but perhaps some smokers do not want to quit nicotine but do want to quit smoking. This is a better option than smoking but one that has not been promoted in New Zealand. NRT has only been offered to smokers as a cessation aid, until recently that is, when the following advertisement placed by Pharmacia appeared in the New Zealand Herald:

> *'Make smokefree areas a non-issue. When you can't smoke, conquer your cravings with Nicorette gum or inhaler'* (NZ Herald, 2001).

Smokers may want to use replacement medications to *gainpartial tobacco abstinence* (Heishman et al., 1997), as is suggested above by Pharmacia. Nicotine, the drug, needs to be separated from the cigarette, which is the delivery vehicle (Sweanor, 1997). Smoking the cigarette causes nearly all the health damage, as although nicotine could potentially have adverse effects on the body, it does not appear to cause cancer or heart disease

(Britton et al., 2000). For smokers to quit smoking and continue using nicotine in another form would be a relatively positive move for their health.

A major problem with nicotine medications to date is their acceptability to smokers (Henningfield et al., 2000). For those who want to continue their nicotine intake but give up smoking, the present nicotine products that are on the market appear to need to provide a quicker uptake into the blood system to be able to compete with cigarettes. There are an increasing percentage of smokers who find the current pharmacological treatments unacceptable (Henningfield et al., 2000). These products have been developed as short-term cessation aids not as a substitute for smoking.

Threshold dose of nicotine to maintain addiction

The tobacco industry publicly questions the idea that there is a threshold dose for nicotine which causes addiction and say a threshold dose cannot be determined (Henningfield et al., 1998). However, a 1982 BAT memo indicates that the tobacco industry is very interested in keep ing the nicotine content at addictive levels:

> *'The simple answer would seem to be to offer the smoker a product with comparatively high nicotine deliveries so that with a minimum of effort he could take the dose of nicotine suitable to his immediate needs.'* (Hurt & Robertson, 1998, p. 1175).

In the 1994 Minnesota Tobacco Trial, examples of the tobacco industry focusing on the *threshold dose* of nicotine required to maintain addiction were presented to the Court (Hurt & Robertson, 1998).

Subpoenaed papers made public by Brown & Williamson and other affiliates of BAT show that as early as 1955 these tobacco companies knew how to remove nicotine from tobacco.

> *'It is possible to remove all of the nicotine from tobacco, but it has been our experience that the resulting cigarette or cigar is an emasculated product which*

> *is neither palatable nor satisfying to the smoker'.* H.R. Hanmer, British American Tobacco Research Director, 1955 (quoted in Associated Press, 1998, p. 318).

It is probable that a threshold level for nicotine addiction does exist (Benowitz & Henningfield, 1994; Borland, 2000). However, it has not yet been established precisely and it would probably vary among smokers (Henningfield et al., 1998). It is also considered technically feasible to manufacture cigarettes below the threshold of addiction (Benowitz & Henningfield, 1994; Henningfield et al., 1998).

It is estimated that 50-70ng of cotinine p er mL is the cutoff for the threshold of addiction (Benowitz & Henningfield, 1994) because the cotinine level for one cigarette is approximately 14 ng/mL and approximately 70 ng/mL for five cigarettes. A cotinine level of 50-70 ng/mL equals a daily intake of 4-6 ng/mL of nicotine.

Discussions around the what the exact level of threshold should be continue within the public health community. Levels of nicotine rangingfrom 0.17 mg(Behm et al., 1993) to 0.4 mgper cigarette have been cited as probably beingbelow the threshold of addiction (Laugesen, 1999). However, if a tobacco product was to be labelled nicotine-free it probably should be lower than 0.17 mg per cigarette. The threshold dose may also need to be lower to ensure young and non-tolerant people are not able access nicotine which may lead to addiction (Henningfield et al., 1998). If the nicotine content was below the threshold of addiction in tobacco, addiction could be avoided (Benowitz & Henningfield, 1994).

2.5 Acceptability of de-nicotinised tobacco

The objective of de-nicotinised cigarettes would be to prevent addiction among new smokers and assist current smokers to quit smoking (Henningfield et al., 1998). The reality is smokers could take up one of several options or combine options, for example:

- Wean themselves off the cigarettes and quit smoking
- Wean themselves off the cigarettes and onto ANDS
- Combine cigarettes and ANDS

De-nicotinised cigarettes would be no less dangerous per cigarette to smoke than nicotine cigarettes and smokers would need to be encouraged to quit smoking or at the very least reduce their smoking.

Nicotine appears to the userto *be pleasurable.* Whether this is simply easingthe withdrawal feelings and / or stress relief and is mistaken for pleasure is a subject of ongoing debate among public health experts. The explanations include:

- ? That smoking *alleviates* stress (Schacter, 1978; Warburton, 1985; Warburton et al., 1991) and poorer smokers counterbalance stress with increased smoking.
- ? That smokers are *already* stressed by nicotine dependence and that increased stress means that the nicotine dependence is even more difficult to cope with, so increased smoking may occur (Cohen & Lichtenstein, 1990; Parrott, 1995; Pomerleau & Pomerleau, 1990). The obverse to this is that in the long run, quitting smoking reduces stress.

Smokers most consistently report that they smoke to alleviate an unpleasant mood state (Britton et al., 2000). However, laboratory studies have failed to find that smoking reduces anxiety (Herbert et al., 2001) or is mood enhancing (Britton et al., 2000). The rewards of smoking may only be avoiding the withdrawal feelings of not smoking (Jarvis, 1994).

The perceived *pleasure* nicotine gives to the smoker could be a barrier to the acceptability of nicotine-free tobacco by consumers. Any government planning to introduce a de-nicotinisation of tobacco policy would want to consider how the smokers would cope with the diminishing levels of nicotine in their cigarettes. R.J. Reynolds researchers knew in the 1970s that a zero nicotine cigarette was not acceptable to consumers. This concurs with the US Surgeon General reporting in 1988 that nicotine-free tobacco did not completely satisfy the cravings of smokers (USDHHS, 1988).

Smokers' cognitive ability improves when they ingest nicotine, which may add to the physiological craving if nicotine is reduced to non-addictive levels in tobacco. However

smoking and nicotine do not improve general learning when compared to non-smokers (USDHHS, 1988).

The tobacco industry has always been aware of the need to maintain nicotine levels in tobacco. A 1982 BAT memo noted:

> *'If delivery levels are reduced too quickly or eventually to a level which is so low that the nicotine is below the threshold of pharmacological activity then it is possible that the smoking habit would be rejected by a large number of smokers...*' (Hurt & Robertson, 1998, p. 1175)

It is likely that smokers would not be prepared to pay reasonably high prices for their cigarettes with no nicotine.

> *'If nicotine delivery is reduced below a threshold satisfaction level, then surely smokers will question more readily, why they are indulging in an expensive habit.'* Dr S.J. Green, British American Tobacco Scientist (quoted in Lewan, 1998, p. 316)

In 1994 it was first suggested that the addiction to nicotine should be accepted but the product should be altered to make it less harmful (Borland & Scollo, 1999). If it is accepted that some smokers will not quit smoking then reducing disease through product regulation could assist in reducing smoking related disease (Raw, 1997).

Research has been undertaken on smokers' responses to de-nicotinised or very low nicotine cigarettes (below what is believed to be the threshold for addiction). De-nicotinised cigarettes do reduce the cravings of smokers (Brauer et al., 2001) who have been abstinent from smoking (Butschky et al., 1995; Gross et al., 1997; Rose & Behm, 1996; Rusted et al., 1996) and produce smoking satisfaction to a similar extent as nicotine-containing cigarettes (Brauer et al., 2001). This research is encouraging for the future of de-nicotinised cigarettes but to be acceptable they may need to be available in a market where there is no access to nicotine cigarettes.

There is a wide range of views on whether significantly reduced nicotine cigarettes would still be pleasurable to smoke. Some public health experts believe they would (Laugesen, 1999a) and this view has been supported by smokers who were part of a focus group testing the soon to be released on the market, Omni Nicotine Free cigarettes. They liked the taste of the tobacco (ENN, 2001). Other 'international experts' believe that nicotine cigarettes deliver nicotine in a very satisfactory way to the smoker (Shatenstein, 1999b).

2.6 Transition from nicotine to de-nicotinised cigarettes

The AM A proposed:

> *'that the AM A encourage the FDA to assert its authority over the manufacture of tobacco products to reduce their addictive potential at the earliest practical time, with a goal for implementation within 5-10 years'* (Douglas, 1998).

The FDA has not been given the authority to regulate nicotine, so the above AM A proposal has stalled, but debate continues on this strategy which could be implemented either in an individual country or internationally. The tobacco industry does not want the FDA to have jurisdiction over nicotine:

> *We obviously need to make sure that we don't do anything in the nicotine delivery device area which could lead to the FDA asserting or obtaining jurisdiction over cigarettes.'* (AssociatedPress, 1998,p. 319)

The tobacco industry have had the technology to reduce nicotine to almost non existent levels for years but have not made any *serious* attempts to market non-addictive tobacco: *'..since the technology apparently exists to reduce nicotine in cigarettes to insignificant levels, why, one is led to ask, does the industry keep nicotine in the cigarettes at all?'*(Kessler, 1994b, p. 153).

Harm reduction is desirable but for population health gains to be achieved through a policy of reducing nicotine in tobacco to non-addictive levels, the appropriate timeframe for the implementation of de-nicotinisation of tobacco is important. Reducing levels of nicotine in tobacco over a number of years slowly would appear to have the most support

(Benowitz & Henningfield, 1994., Henningfield et al., 1998). The suggested timeframe ranges from 28 months (Laugesen, 1999a) to 15 years (Benowitz & Henningfield, 1994). The speed of nicotine reduction would be governed by political acceptability. A comprehensive treatment infrastructure in the health system could manage any adverse health conditions that may occur due to the gradual weaning off nicotine in tobacco (Henningfield et al., 1998).

Recently there have been suggestions that perhaps nicotine could be reduced quickly. The advantage of eliminating it suddenly is that it would significantly reduce the period of time smokers' could increase harm to themselves due to *compensatory oversmoking.* This has been put forward as a consideration, rather than a serious option. The means of implementation of nicotine elimination has not yet been thought out carefully (Shatenstein et al., 2001). Clinical research on nicotine withdrawal and treatment has shown a gradual weaning off nicotine, rather than a sudden nicotine reduction process, is best used to minimise withdrawal symptoms (Henningfield et al., 1999). This could be anything from days to weeks, with the acute withdrawal period for nicotine averaging about four weeks (Heishman et al., 1997).

2.7 Compensatory oversmoking

Compensatory smoking behaviour can occur when addicted smokers switch from higher to lower yield cigarettes or when the number of cigarettes available to them is reduced (Henningfield et al., 1998). This behaviour could be in the form of smoking more intensely thereby increasingthe puff volume, smoking down to the filter thereby increasingthe number of puffs per cigarette and / or smokingmore cigarettes. The tobacco industry has also assisted the smoker to compensate to get more nicotine by placingvents on the filter of cigarettes. These filter vents are tiny perforated holes which are often blocked by smokers, but not by machines. Vent blocking is generally achieved using a smoker's fingers or mouth and allows the smoker to compensate for lowyield nicotine cigarettes (Laugesen, 1997). There may or may not be vents in New Zealand cigarettes but none of the top-ten-selling brand variants and none of the other five filter tip brand variants available for sale in 1996 had visible vents (Laugesen, 1997). Vent

blocking usually occurs in very low tar cigarettes (1-2 mgtar) (Laugesen, 2001 a) but these cigarettes are not available for sale in New Zealand. However, there could be invisible perforations on the filters of cigarettes sold in New Zealand but to date smokers have not been observed to see if they do occlude any such holes.

There is no doubt that compensation occurs when nicotine is reduced or scarce in cigarettes (Laugesen, 2001e) but it would appear that it only occurs partially and / or in the short term (Laugesen, 1997; Scherer, 1999). Even if compensatory behaviour only occurs for a short period of time, there does seem to be a general consensus that smokers modify the way they smoke to maintain a relatively constant intake of nicotine (Blakely & Bates, 1998). Accordingto a nicotine *compensation* hypothesis:

> *'all smokers achieve a specific level of nicotine in their blood, regardless of the FTC nicotine yield of the cigarette smoked'* (Robinson & Pritchard, 1996, p. 282).

To test this hypothesis eight data sets were reviewed which related the usual-brand nicotine yield to blood cotinine concentration with respect to the nicotine-compensation hypothesis. The hypothesis was not supported. These studies were with low nicotine cigarettes but none were with cigarettes with non-addictive levels of nicotine.

It would be possible to avoid compensatory smoking amongst smokers by making nicotine available in alternative delivery systems to tobacco (Henningfield et al., 1998; Warner et al., 1997). This would be particularly applicable if nicotine was reduced significantly in tobacco. Smokers can also learn to reduce the number of toxins they take in when given information on smoking techniques to avoid. Cigarettes could be designed to reduce the level of toxicity to the smoker (Shatenstein et al., 2001).

Tests on Omni Nicotine Free cigarettes found compensatory oversmoking did not occur (Laugesen, 2001d). This provides more optimism for the future which is shared by the American Health Foundation who is hoping to patent a cigarette which does not cause compensatory oversmoking when the nicotine is reduced (Laugesen, 2001d). However,

theoretically compensatory smoking would not be a problem for de-nicotinised cigarettes as the problem occurs from approximately 0.9 mgper yield per cigarette (Laugesen, 1997b) to approximately 0.4 mg when it then becomes difficult to access nicotine (Blakely & Bates, 1998; Henningfield et al., 1998).

Compensation for lack of nicotine is one of the key areas of debate. It is acknowledged by all, that it is apotential concern and barrier to the implementation of de-nicotinisation of tobacco (Henningfield et al., 1998). However, longterm compensatory smoking does appear to decline with lower yield cigarettes (Borland, 1997a). It would be extremely difficult for smokers, if not impossible, to compensate with de-nicotinised cigarettes as there would only be very low levels of nicotine available for extraction (Henningfield et al., 1998). Observational studies of compensatory smoking found that a threshold for FTC nicotine yields probably does exist below which is is difficult to fully compensate for the lack of nicotine. The threshold is thought to be somewhere between 0.2-0.6mg (Blakely & Bates, 1998).

Not all 'international experts' share the view that compensation would not occur at this level, some believe oversmoking may be a serious problem. There is some evidence that de-nicotinised cigarettes would be smoked for longer and with more puffs (Rusted et al., 1996). It is also considered very risky to suggest any policy where the health impact gets worse before it gets better (Jarvis & Bates, 1999a). However, other policy variations may be possible. It could be proposed:

? that there is a voluntary p eriod during whi ch both products are on the market
? Nicotine-free cigarettes are sold at any retail outlets and nicotine cigarettes are sold at restricted outlets
□ Differential taxation on nicotine could be used to encourage consumers to purchase nicotine-free cigarettes □ Reductions in tar in all cigarettes could be regulated at the same time.

2.8 Alternative nicotine delivery systems (ANDS)

Alternative nicotine delivery systems already on the market include smokeless tobacco, oral snuff, *cigalette* (a peppermint flavoured nicotine delivery device) and NRTs, to aid smoking cessation including patches, lozenges, gum and inhalers. The only products available on the New Zealand market are NRT products. Smokeless tobacco has been banned in New Zealand but is legal in Sweden and Norway. It does not expose smokers to the carcinogens and CO in cigarette smoke (GP Weekly, 1994) and is much less dangerous than smoking. However, it is not completely harmless, users increase their risk of cardiovascular disease by 40 percent (Wilson, 2001).

Nicotine is generally considered safe to use in carefully regulated NRT products. NRT is an alternative nicotine delivery system, which is generally used for medicinal purposes to quit smoking. Some ANDS are used purely for recreational purposes. Nicotine delivered in NRT has a slow onset and lower concentrations than nicotine delivered in tobacco and does not impact on already established cardiovascular risk factors (Fagerstrom & Sawe, 1996). Therefore, any nicotine products developed with similar levels of nicotine as in cigarettes, would not pose a threat to the health of smokers who moved from smoking cigarettes to using ANDS or simultaneously smoked de-nicotinised or partially de-nicotinised cigarettes and used ANDS. In fact, it is generally acknowledged that NRT products could have more nicotine in them to provide more *of a hit,* even if the drug was delivered at addictive levels (Button, 2000).

Nicotine is the reason many smokers become addicted to tobacco but the health problems caused by smoking are a result of exposure to thetoxic and carcinogenic constituents in tobacco (Stratton et al., 2001). There has been widespread debate among the 'international experts' on the merits of chronic addicted smokers movingto ANDS to access nicotine, either as a replacement for tobacco or in combination with smoking. There is a possibility that with relatively easy access to NRT products in the USA and Europe that new users could become addicted to nicotine via these products. New Zealand has recently, in theyear 2000, followed a trend to allow nicotine patches and gum to be sold over the counter in supermarkets as well as pharmacies. However it is not

considered there is an addiction risk for these products which are sold over the counter as they contain minimal amounts of nicotine.

There is a need to develop ANDS which are more closely aligned to cigarettes (Henningfield et al., 2000), as many smokers and ex-smokers have negative attitudes towards NRT (Etter & Perneger, 2001). They could, therefore, also have negative attitudes to other ANDS, even if they delivered a more effective *hit* of nicotine. There is no evidence to date, that smokers would consider ANDS as alternatives to smoking (Shatenstein et al., 2001) unless they became more effective nicotine delivery systems. The closer they resemble cigarettes the more likely they are to be addictive. Inhalers may seem addictive but actually the *hit* is via the oral mucosa and more like pipes and cigars, so not as addictive as cigarettes. The nasal spray has the most addictive potential of NRTs and thus is prescribed by doctors (Laugesen, 2001a).

Unfortunately, pharmaceutical companies in most parts of the world face significant barriers to developing new nicotine based products for the reduction of smoking, as they are usually required to be regulated as prescription drugs and not always accessible even to health care providers (Etter & Perneger, 2001). On the other hand tobacco is completely accessible to the public and usually with very little regulation.

2.9 Regulation Requirements

All 'international experts' who have been involved in the discussions on the significant reduction of nicotine in tobacco to non-addictive levels acknowledge that regulation of nicotine is a key issue. There would need to be an agreed threshold level for nicotine addiction which is expected to be close to that identified in the AMA proposal of 0.17 mg per cigarette (Henningfield et al., 1998). Part of the problem with regulation of nicotine is, in tobacco it has largely been exempt from regulation and in other delivery products it has been strictly regulated (Sweanor, 1995). It is also often regulated in two different regulatory systems, one for medicinal purposes and one for non-medicinal. Therefore the most accessible nicotine available to those who are addicted to it, is nicotine in tobacco.

All countries are likely to need a regulatory framework for nicotine. There has been some discussion about whether nicotine should be under the one regulatory system or within present regulatory systems. There is a trend towards a single nicotine regulation system to deal with all nicotine delivery devices (Borland, 1997b; Raw, 1997; BBC, 2000). However, in many countries nicotine in products to aid smoking cessation is regulated under therapeutic legislation and nicotine in tobacco regulated under different (tobacco specific) legislation (Borland, 1997b). This is the case in New Zealand with NRT products being regulated under the Medicines Act 1981 and tobacco products under the Smoke-free Environments Act 1990 (SFEA). Alternative nicotine delivery systems would, at present in New Zealand, not be regulated under any Act. It would therefore make sense and be more practical to ensure the same regulations were applied to cigarette nicotine and ANDS, under the SFEA and the Medicines Act 1981, respectively.

In New Zealand the question needs to be asked, should regulations be strengthened for nicotine delivered in tobacco and weakened for other nicotine which is afterall less hazardous than the nicotine in tobacco? New regulations must be able to cope with all the variations of future products, which will enter the market.

Nicotine replacement therapy has already become more accessible to consumers in New Zealand but it is a smoking cessation aid, not an effective alternative nicotine product for smokers. There is no significant nicotine *hit* from NRT and it could be assumed most smokers would not be interested in moving from cigarettes to NRT as a substitute, if they generally do not find NRT products satisfying (Etter & Perneger, 2001). However, if there were more ANDS on the market that could provide that *hit,* for example, the smokeless tobacco Snus in Sweden, it is likely that smokers could be encouraged to make the transition from smoking to ANDS. Smokers find it easy to switch to Snus, which is a pleasurable recreational drug delivery system for nicotine (Wilson, 2001).

For ANDS to become available on the market quickly and be accessible to smokers, the tight regulations for *clean nicotine* (ANDS) need to be relaxed and *dirty nicotine* (nicotine in smoked tobacco) need to be strictly regulated. Regulations should allow for

graded classification based on total harm caused by the product (Borland, 2001). New Zealand is at least in the enviable situation of being able to develop regulations to reduce the nicotine and tar levels without having to go through the parliamentary process. This has, in fact, already been recommended to the Ministry of Health and the method of implementation could be either through a voluntary agreement with the tobacco industry, regulations under the SFEA or by differential taxation on tar and / or nicotine (Blakely & Bates, 1998). However, the tobacco industry is most unlikely to agree to a voluntary agreement for *meaningful* nicotine reduction as it would probably reduce the sale of cigarettes.

There are challenges in regulation of nicotine in the future but they need to be grappled with urgently as an increased range of nicotine products will be coming into the country over the next few years. At present, smoked tobacco products are unregulated and go straight onto the market with no controls and any ANDS making therapeutic claims can face up to a three year waiting time before they are accessible to consumers. In this environment *dirty nicotine* is available for sale immediately whereas *clean,* less hazardous nicotine can face lengthy delays. Table 2.4 gives an indication of the type of problems the government has to consider in regulating nicotine.

New nicotine products developed in the future will not necessarily be for use as smoking cessation aids but as ANDS, which could be used alongside tobacco products. New nicotine products are already being developed by the tobacco industry but without appropriate regulations in place, these products could increase the harm to the population. There is concern in the international public health community that the tobacco industry is already developing and test marketing new products, which are beginning to be released on the market with very little regulation to control the promotion of these products (Zeller, 2000b). Tobacco companies in the USA have already marketed cigarette-like products and nicotine-free tobacco as risk-reducing tobacco. If, for example, Omni Nicotine Free cigarettes are imported into New Zealand, there is no law to either, stop them coming into the country or to prevent the tobacco industry promoting them as *safer* cigarettes because they are nicotine-free. They are expected to be marketed in the USA as

Table 2.4: Problems of regulation of nicotine

Nicotine	**Act which controls product**	**Current availability**	Expected availability
Nicotine which makes no therapeutic claims (looks like a cigarette)	Not under any Act	Not available	Increased range of alternative nicotine delivery systems (ANDS).
Nicotine for therapeutic effects to treat nicotine dependence.	Medicines Act 1981	Patches / gum available for $5-$10 via quitline or over-the-counter. Nicotine inhaler over pharmacy counter. Nasal sprays are prescription only.	Increased range of NRT products.
Herbal cigarettes with added nicotine. Potentially as harmful as tobacco.	Not under any Act at present but could be legal after the present SOP and SFE Bill is enacted.	Not available	Could be manufactured by a tobacco company with humectants and sweetners etc. Not expected in the short-term.
Tobacco-substitute non-herbal product with nicotine	Not under any Act at present.	Not available	No patents known of.
Marijuana with added nicotine. A highly addictive joint.	Probably under the Misuse of Drugs Act 1975. Use of nicotine for this purpose would have to be specifically obtained.	Not available	Unlikely but if marijuana was legal this could be very popular.
Less harmful modified cigarettes, for example, Eclipse which heats tobacco (Laugesen, 1997).	SFEA	Not available in New Zealand but import and sale legal.	Eclipse currently being test marketed in the United States of America (Wilson, 2001).
Nicotine-free cigarettes	SFEA	Not available	Nicotine-free cigarettes, for example, Omni Nicotine Free.

a smoking cessation aid, which could take Vector Tobacco several months or years to get regulatory approval for them in New Zealand (Laugesen, 2001e). However, if imported as a nicotine-free cigarette they will be available for sale on the market, immediately.

If recreational nicotine is imported there are no regulatory barriers but if medicinal nicotine imported, there are significant barriers. Therefore, strict regulations need to be developed to ensure that newtobacco products and tobacco-related products are controlled by the government, not the tobacco and / or the pharmaceutical industry. There is an enormous discrepancy in the regulation between the two systems. Regulations under therapeutic legislation are generally very strict. There is no regulation for *recreation* nicotine which would be *less hazardous* than nicotine in smoked tobacco but not completely *safe.* Consumers accessing nicotine for recreational purposes is only a matter of time (Laugesen, 1997b). All nicotine delivery-devices should be regulated by the government using a graded classification based on total harm (Borland, 2001).

Whatever decisions are made about regulatory systems, the time has come for strong regulatory frameworks to be developed nationally and internationally (Borland, 1997b). The development of strong regulations would have a twofold effect:

- ? It would increase the likelihood of a significant nicotine reduction policy being effective in reducing population harm and
- ? It would pave the way for the development of new nicotine products as smoking cessation aids and / or as ANDS.

Regulation of nicotine in New Zealand

The government needs to be considering the introduction of population harm reduction strategies and specifically undertaking research in the regulation of nicotine in tobacco and ANDS. The first step in theprocess is that thetobacco industry should be required to provide full disclosure of the ingredients in tobacco, brand by brand to a regulatory agency (Stratton et al, 2001). Theprocess to enable this to happen has begun through the parliamentary system in New Zealand. The government must know what is in cigarettes

to begin to make effective regulations. The next step would be to make the decision whether New Zealand was going to move towards eliminating nicotine from tobacco.

If it was to follow the option of de-nicotinisation of tobacco, a timeframe would need to be set to reduce the nicotine. The favoured option has generally been to reduce the nicotine over a long period of time but there is evidence smokers could probably cope with an abrupt switch using nicotine skin patches to ease the transition (Rose & Behm, 1996). If this was the case the de-nicotinisation of tobacco process could be avoided and nicotine-free cigarettes could be available for sale within a matter of days which would probably eliminate compensatory smoking entirely. However, on a national scale this would probably not be acceptable, as not everyone would feel like switching to nicotine-free cigarettes on a given date. It would be a huge social upheaval with demonstrations and riots with many sympathising with the smokers (Laugesen, 2001a).

Therefore, the most acceptable but not the most ideal policy would be to gradually reduce the nicotine levels over a reasonable period of time. The gradual reduction would cause compensatory oversmoking but perhaps there could be an abrupt reduction on a given day with a gradual reduction to cross thethreshold over a period of months oryears (Laugesen, 2001a). If this was supported by a full media campaign duringthe period of reduction the likely negative health impact could be minimised. There would also need to be regular independent testing of the tobacco to ensure the tobacco industry were meeting the time and nicotine content reduction requirements.

Packaging, labelling, advertising, distribution, sale and promotion of all nicotine products would need to be carefully regulated under a *not false or misleading standard* (Stratton et al., 2001). Classification for different products could be graded based on total harm, to encourage the manufacture of *less hazardous* products (Borland, 2001). The marketing of these products would need to be strictly controlled (Raw, 1997). Competition for new products should be encouraged but it should be:

> *'Competition to produce less harmful products NOT competition regardless of the harm'* (Borland, 2001, p. 10).

New Zealand could as a starting point, license all nicotine products and approval would be a condition of sale. In developing a regulatory framework to regulate nicotine it must include the capacity to monitor and research nicotine products already on the market and those coming onto the market. This would guide the control of production, packaging, marketing and sale of all nicotine products . Penalties for violation of regulations should be severe (Borland, 2001). The regulations would need to be robust to ensure the same mistakes were not repeated as (Borland, 2000) with *light* and *mild* nicotine cigarettes which implied a *safer* cigarette through the packaging and labelling. The message to smokers must continue to encourage them to quit or reduce the harm associated with their smoking (Zeller, 2000b).

Regulations would be required to cover, all nicotine in smoked tobacco and ANDS, which have been manufactured or imported for sale in New Zealand. Duty free cigarettes would be required to comply with New Zealand regulations. Significantly reduced nicotine cigarettes and ANDS could be the key to providing public health gains but there are pitfalls and the challenge for regulators is to avoid those pitfalls (Slade and Henningfield, 1998).

2.10 Public health implications

Reducing nicotine in tobacco to non-addictive levels would appear to be an option worthy of consideration as a strategy to reduce the prevalence rate of smoking and the consumption of tobacco. However, there is a risk that in implementing the de-nicotinisation of tobacco process there will be unintended consequences. These consequences could reduce the benefits that might otherwise occur in a given population (Stratton et al., 2001). The benefits could include decreased morbidity, mortality, secondhand smoke exposure, healthcare expenditure and increased smoking cessation. On the other hand there could be decreased smoking cessation, increased initiation (Hughes, 1995) and a return to the market by ex-smokers.

Making cigarettes *less hazardous* could be seen as a strategy that *sends the wrong message* (Reuter & MacCoun, 1995). This implies, that population harm reduction strategies need to include strong messages encouraging smokers to quit smoking. Tobacco products that are *less hazardous* are *still hazardous* and need to be strictly regulated to ensure these products do not actually increase tobacco use in some population groups and / or decrease smoking cessation (Hughes, 1995).

If nicotine was eliminated from tobacco, it is considered young people would not become addicted while they were experimenting with smoking and therefore could give up smoking when they wanted to. Current smokers, who wanted to quit, would find it easier to quit. However, young people who might not otherwise have taken up smoking may be drawn in, if they thought the cigarettes were no longer addictive, believingthat smoking is a relatively safe option without the nicotine. Ex-smokers could also smoke an occasional cigarette, which should not be a problem as they would not become addicted (Laugesen, 2001b).

Elimination of nicotine in tobacco is intended to reduce the total harm caused by tobacco use by decreasing drug dependence for those who continue to use tobacco products and those who stop using tobacco products. However, the total harm cannot be estimated in advance as it is difficult to quantify the size of the potential negative consequences. These could be counteracted with:

- A general and medical education campaign
- A robust treatment infrastructure
- Accessible, affordable ANDS
- A research infrastructure
- Consistent regulation of all nicotine-delivering products (Henningfield et al., 1998)

2.11 Unintended consequences

When a new policy is implemented there are usually some unintended consequences. Some of these can be anticipated but not all. The anticipated unintended consequences of

the introduction of a de-nicotinisation of tobacco policy are an increased black market with associated crime and the increased sale of cigarettes through the internet, telephone sales and mail order. The full extent of these consequences would be dependent on the regulations and support provided by other policies implemented as part of the national tobacco control programme.

Black market activity

A nicotine reduction strategy is likely to be the impetus for an increased black market given that there would be a level of unacceptability of de-nicotinised cigarettes among consumers (Butschky et al., 1995). There could be a backlash from some smokers who will look elsewhere for nicotine cigarettes. De-nicotinisation of tobacco has already attracted *aprohibition* label (Las Vegas Review, 1997).

It is not an *all or nothing* issue. There is uncertainty on the size of the black market problem. Policy makers would have to make a judgement about the possible increase in a black market (Henningfield, 1998). It is hard to know whetherthere would be an increase in smuggling activity. It could be assumed that there would be, given that smokers would not be able to access their preferred nicotine cigarettes. Anti-smuggling law enforcement activities may need to be intensified, at least initially, to counteract an expected increase in the smuggling of nicotine cigarettes. The cooperation of tobacco manufacturers could be enlisted (Henningfield et al., 1998) although the tobacco manufacturers are unlikely to co-operate in a strategy which could well bankrupt them (Shatenstein, 1999b). New Zealand is well set up to deal with smuggling with x-rays and highly trained *sniffer* dogs which have greatly strengthened the border defences (DOC, 2001). Seaports and harbours would also require surveillance (Laugesen, 2001b) which should not be a problem as New Zealand's systems for protecting its borders are acknowledged to be amongthe best in the world (DOC, 2001).

There would in all probability be an upsurge in crime to meet the demand in high nicotine black market cigarettes. Crime could be associated with tobacco in the same way it is

with other addictive drugs and illicit drugs (Blakely and Bates, 1998). This would need to be factored into any programme to eliminate nicotine in tobacco.

The internet, mail order and telephone sales

A search of the internet to purchase cigarettes was undertaken and cigarettes and cigars can easily be purchased. These are generally discounted and can be purchased from overseas without paying goods and services tax. As well there are the general sites that sell cigarettes online within New Zealand, for example, Woolworths Supermarkets. Woolworths provides a delivery service for products purchased online which include cigarettes. However, if a de-nicotinisation of tobacco policy was introduced in New Zealand then Woolworths would have to sell the de-nicotinised cigarettes so there should be no access through them to nicotine cigarettes. Purchasing nicotine cigarettes from overseas online would still be an option, but any de-nicotinisation of tobacco policy would ban imports of nicotine cigarettes.

The sale of nicotine cigarettes would be difficult to monitor, particularly through the internet, although the sites would be known as all incoming mail into New Zealand comes in through the Auckland mail room. This mail could be intervened at the mail centre. New York's Legislature has recently banned the sale of cigarettes on the worldwide web, through the phone or by mail order saying it poses a *serious threat* to public health (Fairclough, 2000). This public health threat would be increased significantly if nicotine cigarettes could be accessed from countries that had not legislated for the reduction of nicotine in tobacco to non-addictive levels.

2.12 International vs national policy

There is no doubt that if elimination of nicotine in cigarettes was to become international policy there would have more likelihood it would be successful. The usual method of progressing tobacco control strategies is country by country, for example, tobacco advertising bans and smokefree environments, the progress emanates from one country and spreads to another. However it would be difficult for any country to develop a de-nicotinisation of tobacco policy without international support. NewZealand is a country

that could be a good place *to pilot the* introduction of a significant nicotine reduction strategy in tobacco. This is largely due to the fact the country is surrounded by water, is reasonably isolated, has a very minimal black market (Laugesen, 1997a) and a reasonably strong tobacco control policy with particularly supportive programmes for those wishing to quit smoking. There is political support from the Labour / Alliance Coalition government and the political will to reduce the population harm caused by tobacco.

Internationally, there is support for countries to implement strong regulations and to support effective proposals in the Framework Convention of Tobacco Control (FCTC) presently being developed by the World Health Organisation (WHO). Tobacco is emerging as the single most important public health hazard, providing the impetus needed for individual countries to develop strong regulations. According to Dr Bruntland, Director-General of WHO:

> *'Governments must push for the inclusion of effective tobacco content and design controls in the protocols to the FCTC, the time for meaningful and integrated tobacco control is now'* (WHO, 1999b, p.1).

2.13 What important questions remain unanswered?

Whilst there is clearly support from the research to move forward with a population harm reduction model for tobacco use, there does not appear to be a consensus among 'international experts' about whether nicotine levels in tobacco should be reduced to non-addictive levels. The debate needs to continue and more research is required to provide evidence to support either reducing nicotine and / or tar levels significantly.

The difficulty for those working in the field of tobacco control is that events are overtaking them. While the debate goes on there are still questions (Blakely & Bates, 1998) about what kind of research evidence should be driving the debate and the regulatory decisions which will need to be made (Zeller, 2000a). Further research will continue but in the meantime governments need to take action because tobacco and nicotine products are coming onto the market without the support of strong regulatory systems.

The ANDS coming onto the market need to be regulated but most regulation systems subject the most harmful products to little regulation and the least hazardous products are stringently regulated (Sweanor, 1995). There is a very high risk that once again, the tobacco industry is leading the way with PREPs. The tobacco industry first began to address health concerns following World War II, when filter cigarettes were developed (Blakely & Bates, 1998) followed by *light* and *mild* cigarettes (Stratton et al, 2001). Both these tobacco product modifications have not reduced the overall harm to the population. Smokers have been able to modify their smoking behaviour to maintain their intake of tobacco constituents. The availability of *less dangerous* tobacco products can lead to more people smoking outweighing health gains for individuals (Blakely & Bates, 1998). Canada has recently taken a lead in announcing that the federal government will ban *light* and *mild* tobacco labels:

> *'because they give consumers a deceiving assurance the products are safer than regular cigarettes'* Canadian Health Minister, Allan Rock (quoted in Shatenstein, 2001, p.1).

If a de-nicotinisation of tobacco policy was introduced into the present environment it would add to the current imbalance between medicinal and non-medicinal nicotine regulation. There is a belief that history would repeat itself, with no obvious health benefit to the population. The way forward, is for regulatory authorities to develop expertise on tobacco and nicotine issues (Sweanor, 1995). Tobacco and pharmaceutical companies should be forced to minimise the harmfulness of their products, to inform consumers of the health risks, to promote ANDS includingNRT in away to maximise public health benefit.

The theoretical proposal to eliminate nicotine in tobacco has been researched and debated amongthe 'international experts'. It could be implemented internationally but it may be that it is going to take one country to take the lead on this strategy and others could follow, if an evaluation found there were significant health benefits on a population level. New Zealand could be a good country to pilot such a strategy. The most likely scenario

will be that individual countries will modestly reduce levels of nicotine and tar in tobacco through regulation as in Europe. While this is occurring, research to assist in providing a clearer picture on the future could continue.

It would appear that smokers would accept de-nicotinised cigarettes to a limited extent but they would probably not choose to do so. However, given 29% of cigarettes sold in New Zealand in the year 2000 were labelled *light* or *mild* (or a variation on that terminology) (Laugesen, 2001a) New Zealand smokers are probably concerned about their health. They may have shifted to the *light* and *mild* cigarettes to try and minimise their health concerns. Therefore, more smokers may support anew strategy if they thought it would address their health concerns. Omni Nicotine Free cigarettes retain the full taste of nicotine cigarettes which gives some hope for the future acceptability of de-nicotinised and nicotine-free cigarettes among smokers (Laugesen, 2001f).

At this stage, it would appear there is not enough evidence for the 'international experts' to be convinced a de-nicotinisation of tobacco strategy is the way forward (Bates, 2000; Shatenstein, 1999b). Although, harm reduction in tobacco use as a strategy is generally supported by the 'international experts' (Jarvis & Bates, 1999a., Henningfield, 1995). The question now, is how should a harm reduction strategy be progressed? It may be that a choice of nicotine-free and nicotine cigarettes could be necessary if a de-nicotinisation of tobacco policy is not acceptable among smokers. This could occur one step at a time with public approval and finally lead to only nicotine-free cigarettes available on the market after a certain period of time. There would then be no need to work through the de-nicotinising of tobacco process as smokers would have the opportunity to wean themselves off nicotine in the nicotine-free cigarettes. This would counter also some of the compensatory smoking arguments.

Tobacco documents indicate the tobacco industry is very concerned that nicotine will be eliminated from tobacco (Hurt & Robertson, 1998; Lewan, 1998). There appears to be no deviation on this view between tobacco companies. They are united in believing the removal of nicotine would spell the end of smoking. This does notfitwith the

'international expert' view which is still very unclear about whether to support lowering the harmfulness of tobacco or adding a less harmful but dependency-creating product (ANDS) (Stratton et al., 2001). With the tobacco industry consistently showing concern about the removal of nicotine from tobacco, it should be evidence of the strategy's effectiveness. However, the industry also likens the approach to prohibition as do some of the critics (Las Vegas Review, 1997; Shatenstein et al., 2001) or at the very least, de facto prohibition (Shatenstein et al., 2001) which is not a favoured approach by tobacco control advocates. This opposition, particularly from some 'international experts', could perhaps be overcome with a trial period of nicotine-free cigarettes as optional cessation aids, sold alongside nicotine cigarettes.

The major concern with the de-nicotinisation of tobacco strategy is the issue of compensatory smoking behaviour. The problem of compensatory smoking could be compounded because the de-nicotinisation of tobacco process could take years before the threshold of addiction was reached. Once the estimated threshold of addiction was reached it would be difficult to fully compensate for nicotine (Blakely & Bates, 1998; Borland, 1997a). The use of ANDS could be one way of avoiding compensatory smoking behaviour among smokers (Henningfield et al., 1998; Henningfield et al., 1999; Warner et al., 1997).

Recently the safety of nicotine has been questioned (Hecht et al., 2000; Heeschan et al., 2001). Studies found:

- ? Nicotine in NRT can be metabolised into a lung cancer precursor
- ? Nicotine stimulates generation of blood vessels that could have negative effects on atherosclerosis and tumour growth.

These studies have not been considered highly credible by the 'international experts' (Chapman, 2000; Fagerstrom, 2001). Research of this nature is a concern as many smokers already have inadequate knowledge and negative attitudes to NRT (Etter & Perneger, 2001). Perceived harmfulness of nicotine could be a barrier for smokers wishing to shift from smoking to using ANDS. They may require reassurance that

nicotine is less hazardous in ANDS than in smoked tobacco particularly if they are considering shifting to using nicotine long term. While nobody believes nicotine is 100 percent safe, it is worrying if smokers believe nicotine, as a stand-alone product, is dangerous. This could be a significant barrier to improving public health in the future.

Blood nicotine levels in NRT users are five times less than 30/day smokers (Chapman, 2000). It would make sense that NRT and smoking could continue together without the nicotine causing harm to the smoker, if the smoker reduced by six cigarettes per day. If the smoker smoked at the same rate there would be no guarantee that the excess nicotine intake would not cause harm. This would need to be researched and is not yet being recommended by 'international experts' (Kozlowski et al., 2001). It is probable that chronic addicted smokers would require their nicotine intake to be *topped up* if the nicotine was eliminated from cigarettes.

Leading regulators, scientists and activists in tobacco control agree there needs to be a review of the current regulatory imbalance that allows open access to cigarettes but strict regulation of pharmaceutical smoking cessation aids (WHO, 1999a). This lack of consistency is a barrier to tobacco control (Borland, 1997b). There is ongoing deb ate about regulatory systems. Whether a single regulatory system is better than separate systems. This is probably very much dependent on the regulatory systems that are already in place in different countries. In New Zealand, it would probably be more practical and acceptable to government to work within existing legislation.

Although considerable research has been devoted to eliminating nicotine from tobacco there is still no clear direction for the future. The research has not been able to completely alleviate concerns about compensatory smoking, or the possibility that the uptake of smoking could increase and / or smokers could continue to smoke cigarettes rather than quit smoking. The introduction of *safer* cigarettes in the past has not reduced population harm (Blakely & Bates, 1998; Warner et al., 1997).

The question mark that remains over the size of the likely black market is an area of concern, particularly with the expected growth of cigarette sales on the internet. The State of New York has banned the sale of cigarettes on the internet (Fairclough, 2000), but it could be very difficult to enforce. It is certainly easy enough to buy cigarettes through the internet but it does not appear to be a practice commonly employed by smokers in New Zealand. Perhaps, there is no reason to, but this could change depending on future government policy. If it was so small a scale to be concealable, it may not be worth worrying about.

There is no doubt that until the 'international experts' in tobacco control can agree on the direction for the type of total harm minimisation strategy, it is going to be difficult for any government to pursue a de-nicotinisation of tobacco policy. However there are several components of the strategy that have general support, which could be enough to begin down apath ofpopulation harm reduction. We are at a turning point, but which is the way forward?

KEY POINTS

1. Reducing nicotine to non-addictive levels as a population harm reduction strategy was proposed by the AM A (Henningfield et al., 1998), endorsed and supported by the BMA. It has been endorsed and opposed equally by many reputable international medical / public health groups and individual experts.

2. Significantly reducing nicotine levels in tobacco, to below the threshold of addiction, would need to be part of a comprehensive national tobacco control programme (Stratton et al., 2001) with strong surveillance, supportive research and a regulatory approach throughout the process.

3. De-nicotinisation of tobacco should prevent addiction in new smokers and assist smokers to quit smoking. This policy has thepotential to significantly reduce death and disease caused by smoking in the future.

4. Alternative nicotine delivery systems would need to be accessible to smokers as they were weaned off nicotine in smoked tobacco. This would have the likely effect of reducingthe incidence of compensatory oversmoking (Henningfield et al., 1998).

5. There is a risk that a de-nicotinisation of tobacco policy could result in increased total harm to the population caused by compensatory oversmoking, an increase in the uptake of smoking and / or smokers reducing rather than quitting smoking. In the long term, there could be a reduced health risk to individuals but an increased risk for the health of the population (Stratton et al., 2001).

6. Tests on Omni Nicotine Free cigarettes found compensatory oversmoking did not occur (Laugesen, 2001d). Compensatory smoking behaviour is a problem, which would probably only occur during the process of de-nicotinising tobacco.

7. The flow on effect of reducing nicotine levels in smoked tobacco would almost certainly be an increase in black market activity and associated crime (Blakely & Bates, 1998). Nicotine cigarettes could be accessed through the internet, mail order and / or telephone sales. The scale of these problems would increase if the policy was adopted in one country only.

8. The major problem facing proponents of a significant nicotine reduction in tobacco policy will be achieving political, industry and public support to implement this option (Blakely & Bates, 1998).

CHAPTER 3
METHODOLOGY

In this chapter, I will initially discuss the theoretical perspective from which this research is based and the selection of the research methodology. This will be followed by a description of the objectives; the sample and sample plan; preparation for interviewing and the interview schedule and data analysis.

The research objectives relate to the overall objectives as described in chapter one. The aim of the research methodology was to find out from key informants what they think and how they feel about the introduction and likely implications of a de-nicotinisation of tobacco policy. The findings will then be derived from the raw data provided by the interviews and with the insights from the literature sources, the overall obj ective of the thesis, to determine the acceptability of a de-nicotinisation of tobacco policy, should be achieved.

The research objectives were:

1. To find out a range of views of smokers and ex-smokers from different adult population groups, on a de-nicotinisation of tobacco policy.
2. To seek the views of individuals, who have expert knowledge or a strong interest in tobacco control, on the likely acceptability, impact and implications of a de-nicotinisation of tobacco policy.

I wished to explore the idea of eliminating nicotine from tobacco with smokers and ex-smokers, from their perspective, as they believed they would experience it. Similarly, withpublic health experts, I wished to explore the support for such a policy. How it could be implemented and what the implications might be?

The methodology selected for this study to obtain primary data was qualitative research. The reason for the selection of this methodology was that the focus of the research was on the acceptability of apolicy and determining a process for implementation of that

policy, if it was considered acceptable. It required a detailed description of theprocess and according to Miles and Huberman:

> *'the strength of qualitative data is that it is rich and holistic with strong potential for revealing complexity nested in a real context'* (Rudestam & Newton, 2000, Appendix O)

The qualitative method employed in this research accommodated the complex issues and different perspectives of the two distinct groups of key informants. Whilst the public health experts had either considerable expertise or a strong interest in tobacco control, the smokers and ex-smokers for the purposes of this research were also *experts.* Their expertise lay in the depth of their feelings and understanding of smoking issues as demonstrated below:

> *'The purpose of interviewing, then, is to allow us to enter the other person's perspective.'* (Patton, 1987,p. 109).

There are advantages and disadvantages in using the interview process as a research strategy. Whilst it is a flexible and adaptable way of finding things out, there can be concerns about reliability (Robson, 1993).

The general inductive approach was used for data analysis. It is sometimes described as *inductive* but that label is not always used (HRMAS, 1999). There was no organised structure or assumptions made about the data prior to beginning the research but there were questions to be answered. There were initial expectations that:

- Smokers would support a significant reduction of nicotine in tobacco to non-addictive levels provided policies were developed by the government which would assist them in the transition from nicotine to de-nicotinised cigarettes.
- Policy makers would be prepared to reduce levels of nicotine but not to non-addictive levels. They would require more evidence and research to be assured that this was the right strategy to significantly reduce the total harm caused by smoking in New Zealand.

3.1 Sampling Plan

The sampling method used was purposive sampling which is a non-random method employed to target key informants with specific characteristics (Bowling, 1997). After consultation with my supervisors and George Thomson, a Ph D student (presently writing a thesis on tobacco control policy) on appropriate key informants to interview, I made the decision to interview two distinct groups of people. The first group identified were *smokers and ex-smokers* who would provide expert knowledge from a consumer perspective. The second group identified were *public health experts* who could contribute knowledge and insight from their *expertise in the field.* The subjects in both groups were selected because they could:

> *' ...illuminate the evolving phenomenon being studied.. '* (Sandelowski et al., 1989, p. 79).

The selection process identified a mix of smokers and ex-smokers from different adult populations. It was decided the smokers and ex-smokers would be from three workplaces (a blue collar, a white collar, and a mainly female), a bowling club, a university, Maori smokers from a marae, a small community and through established networks. The aim was to interview 63 smokers and ex-smokers over 18 years of age including a mix of: male; female; Maori; non-Maori; smokers and ex-smokers under and over 25 years and smokers who smoke under and over 15 cigarettes a day.

Criteria for selection was developed for the key informants. The criteria was that the public health experts had expert knowledge or a strong interest in tobacco control, the smokers smoked at least one cigarette per day and were over 18 years of age and the ex-smokers had quit smoking for more than six months, less than five years and were over 18 years of age.

Recruiting smokers and ex-smokers

A letter was sent to BHP NZ Steel, Seabreeze Fashions and KPMG requesting permission, from each Chief Executive Officer (CEO), to allow focus group interviews to

take place in their workplaces during work time. A copy of the consent form, a copy of the participant information sheet, a participant information sheet for the CEO of a company4 and a notice to recruit smokers5 was enclosed with the letter. A letter was also sent to the President of the Onehunga Bowling Club, the Vice Chancellor of Auckland University of Technology and the Tumuaki of Te Ara Poutama seeking permission to facilitate focus group interviews in all three premises. The CEOs and management staff were requested to display the notices on the staff and student noticeboards. The notices directed potential key informants to telephone the researcher if they were interested in participating in a focus group interview.

In recognition of the Treaty of Waitangi consultation took place with DrMarewa Glover, a Maori psychologist and smoking cessation expert prior to writing to the Tumuaki of the university. She provided advice on whom to contact and the language in the panui (invitation)6 to be displayed on the noticeboard at Te Ara Poutama.

A letter was sent to the Manager of Waiheke Health Trust to request permission to display a notice on the Health Trust noticeboard to recruit smokers and ex-smokers for a focus group interview.

An email was sent to two potential key informants. One was followed up with a telephone call. They were invited to participate in a focus group interview and encouraged to invite other smokers and ex-smokers to participate in a focus group interview. These contacts were accessed through ASH (action on smoking and health)[7] networks.

One week after the letters were sent to the employers and management, a telephone call was made to each of them to ask if they would first, place the recruitment notice on their

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Appendix 1 - Consent form
Appendix 2 -Participant information sheet
[4] Appendix 3 -Participant information sheet for a CEO of a company
[5] Appendix 4 - Notice to recruit smokers and ex-smokers
[6] Appendix 5 -Panui
[7] Note - ASH is the researcher's place of employment

staff noticeboard and second, release staff to participate in the focus group interviews. They were all very supportive except for the CEO of KPMG who informed the researcher, that most of the employees worked off-site and it would be very difficult to organise a time for them all to meet. The remainder of the management staff agreed to display the notices and thepanui. I placed a notice on the student noticeboard at the University. The Waiheke Health Trust also placed an advertisement in the local community paper to recruit smokers and ex-smokers. They have a *slot* in the paper on a weekly basis so placed the advertisement free-of-charge.

There was no response to any of the notices either on the noticeboards or in the community paper. It was therefore arranged for each notice be replaced with a second notice offering a $20 compact disc (CD), book or petrol voucher to each potential key informant to encourage smokers and ex-smokers to participate in focus group interviews. There was still no response.

At this point, as I had no focus groups organised I decided on a second plan which involved a combination of convenience sampling and the snowballing technique to identify potential key informants (Bowling, 1997). Convenience sampling involves subjects who are easy to recruit and are likely to respond. Snowballing is used by recruiting initial participants who are willing to be interviewed and will then recruit others. It was also clear at this stage, that it was going to be very difficult to recruit focus groups and a decision was made therefore to recruit individuals, with the flexibility to include focus groups if they occurred on a spontaneous basis. Another more crucial issue was fast developing and that was a lack of time. The interviews needed to take place to ensure I had enough time to process and analyse the data within thetimeframe set by the Master of Public Health (MPH) programme.

This revised sampling methodology proved effective. Twenty-one smokers were interviewed including a group of seven from Northland Poly tech in Kaitaia; a group of three, a group of four and three individuals from Beca International Consultants Ltd in Auckland; an individual from Nelson Pine in Auckland; two individuals from two

different offices in the same building in Auckland and a retailer from BOC Gas & Gear, a retail outlet in Auckland. One focus group of four occurred spontaneously as I had arranged to meet with a smoker at the *smoko table* in the basement of her workplace. There just happened to be three other smokers sitting at the table who were interested in participating in the interview. All the smokers were interviewed face-to-face. Two ex-smokers were recruited through ASH networks and were interviewed on speaker phone, one from Auckland and one from Tairua.

Recruiting public health experts

A letter including a consent form and a participant information sheet[8] was sent to each identified public health expert to request their consent to either a face-to-face or a telephone interview. Each potential key informant was telephoned for his or her response to the letter approximately one week after receiving it.

All the public health experts consented to being interviewed except:

- An academic who referred the researcher to another academic in the Division of Community Health, University of Auckland.
- A health reporter from Television New Zealand (TVNZ), Christchurch because the management had banned staff involvement in any activity that could politically be misconstrued and potentially be a conflict of interest.
- An associate health spokesperson, for the Lab our/Alliance Coalition, also because of a potential conflict of interest.

The final group of smokers and ex-smokers were very different to the group initially planned and the number was significantly fewer due to the fact that the focus groups could not be organised. I mainly interviewed individuals. However the group of public health experts was almost exactly as planned. The respondents interviewed were all involved in public health or were smokers and ex-smokers.

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[8] Appendix 6 -Participant information sheet for public health experts

3.2 Final sample

Thirty-seven key informants were interviewed including: Fourteen public health experts, 21 smokers and two ex-smokers. Their details are outlined in Table 3.1.

Table 3.1: Description of key informants

Key informants	Description
Public Health Experts	
4 government officials	From the Prime Minister's Department; Ministry of Health including Medsafe, (Auckland and Wellington)
3 politicians	Health spokespeople for the Alliance, Labour and National political parties (Otaki and Wellington)
3 media people	Health reporters from the Sunday Star Times (Wellington), New Zealand Herald and Independent Radio News (IRN - Auckland)
3 Academics/tobacco control advocates	From Wellington School of Medicine, and the Division of Community Health, University of Auckland and the Smokefree Coalition
Smokers and ex-smokers	
21 smokers	7 from Northland Polytech, 10 from Beca International Consultants Ltd, 1 from Nelson Pine; 2 from the same office building; 1 from BOC Gas & Gear, including7 male, 14 female; 5 under 25 years old, 16 over 25 years old; 6 Maori, 15 non-Maori; 10 who smoked more than 15 cigarettes per day and 11 who smoked fewer than 15 cigarettes per day
2 ex-smokers	2 through ASH networks including: 1 female who had quit smoking for 7 months, from Tairua; 1 male smoker who had quit smoking for 6 months, from Auckland.

3.3 Preparation for interviews

Ethics approval was granted by the University of Auckland Human Subjects Ethics Committee.

The key informants were invited to participate in this research as part of my thesis for the MPH. They were informed that I worked for ASH. My supervisors advised me that I

should inform them I was an employee of ASH, as they may recognise my name or believe I was undertaking the research on behalf of ASH. Responses could be biased from the key informants if they thought the research was for ASH. This potential conflict of interest was included in the participant information sheet sent to the participants prior to the interview.

I was also advised to contract a facilitator to facilitate two or three of the group interviews to ensure there was a lack of bias. As I have worked in tobacco control for approximately eight years, I do have well-established ideologies on many of the arguments for and against particular tobacco control interventions. The subjectivity of the researcher is acknowledged. It was necessary therefore to try to set aside previously held points of view and endeavour to remain impartial during the interview process and in particular, in response to any questions from key informants.

The intention of the research plan was that Dr Glover and Velma McClellan (Health Researcher) would facilitate some of the focus group interviews. Unfortunately, this did not occur due to the lack of response from the Maori students to a panui posted on the notice board at Te Ara Poutama, Auckland University of Technology and the focus groups through workplaces and the community could not be arranged. In the end, I was able to organise a focus group interview in Kaitaia but the extra cost of flying or driving a facilitator from Auckland to Kaitaia was prohibitive.

I planned to facilitate a pilot focus group interview with smokers and ex-smokers and an individual interview with a public health expert but I actually only managed to organise an interview with an academic from the Division of Community Health in Auckland. A focus group of smokers and ex-smokers could not be organised in a suitable timeframe so there was no pilot group interview. The questions forpublic health experts were slightly modified following the pilot interview as one or two were too long.

3.4 The Interviews

The format of the interviews was open-ended with a flexible agenda and open ended semi-structured questions.[9] There was a variation in the questions for the smoker/ex-smoker group and the questions for thepublic health experts. Thetimeframe of the interviews was approximately 45 minutes. When a face-to-face interview took place, a suitable venue with access to refreshments was organised and if necessary booked. All smokers and ex-smokers were provided with a participant information sheet, a group participant profile form10 and a consent form which was signed prior to the group interview, then returned to me either on the day of the interview or through the mail and stored in a locked cabinet.

The interviews took place over a six month period. For each interview a probe sheet of probes was developed to support the questions. This served as a reminder and a guide to ensure all areas of interest were covered within the interview. The group participant profile was filled in by all the smokers and ex-smokers whether they were part of a group or not. I found it provided extra details about them that I was not able to comfortably gain through the interview process. Although it was not a pre-requisite for the interview none of the key informants refused to fill in the form. All the interviews were audiotaped with the consent of the participants.

Just prior to each interview particularly with the smokers and ex-smokers I spoke informally with them to gauge their level of understanding of nicotine and its role in the addiction process of smoking. There is quite a general misunderstanding among the public, that nicotine is one of the major harmful constituents in tobacco. Whilst it is not completely harmless and it does have toxic properties they are far fewer and less serious than other toxic constituents in tobacco (Stratton et al., 2001). I needed to be sure that key informants were aware of the difference b etween nicotine and other toxic constituents in cigarettes, as it would affect some of their responses in the interview. I did not use the

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Appendix 7 - Questions for smokers, ex-smokers and public health experts [10] Appendix 8 - Participant profile for smokers and ex-smokers to fill in (not compulsory)

terminology 'de-nicotinisation of tobacco' with the smokers but rather 'removing the nicotine to non-addictive levels in tobacco'. The public health experts were given a brief explanation of the de-nicotinisation of tobacco process following the background questions. The fluidity of the interviewing process and open-ended questions allowed for explanation and clarification when required throughout the interviews.

Most of the key informants, particularly the smokers and ex-smokers, were provided with a small offering, either in the form of refreshments and/or vouchers for CDs, books or petrol. All the individuals and a member of each focus group were sent thank you letters or cards with the copy of the transcription of their interview and asked for feedback.

Processing of interviews

After each interview, the tape recording was checked for quality, notes were taken throughout the interviews just in case the tape recorder failed to record the interview. The interviews undertaken by speakerphone provided the best recording and despite concerns about using this method of interviewing, it was very successful. In many ways the telephone interviews were much more succinct and the key informants appeared to be more focused in their responses to the questions than those interviewed face-to-face. In the face-to-face and group interviews it was very easy for key informants to wander off the topic, which did provide for a more relaxed interview and enable free discussion particularly in the groups but it also ensured a more arduous task in the transcription of the interviews. My inexperience as an interviewer was apparent in the initial interviews, which were much longer and not as rich in information as later interviews.

3.5 Data analysis

I transcribed the initial interviews and found that whilst the process was extremely laborious, it also gave me good insight into the raw data, which was useful for the data analysis. A general inductive approach was used to analyse the qualitative data collected through the interview process. This approach was developed as a systematic procedure, where the analysis was guided by the specific obj ectives of the research (HRM AS, 1999), which were identified at the beginning of this chapter. It was important to assess the

trustworthiness of the data at various stages of the analysis. Initially this was undertaken by sending the transcripts back to the key informants to validate and make comments. The transcripts of the interviews needed to represent what the key informants wished to relate. Some public health experts responded but did not require any changes. None of the smokers or ex-smokers responded.

To analyse the data using the general inductive approach, I immersed my self in the data, exploring the text to identify themes and categories, without the burden of a tightly formulated hypothesis. This approach involved moving from a specific theory and working towards the development of generalised concepts (Rudestam & Newton, 2000).

I then began the process of coding, which involved re-immersingmyself in the raw data and identifying text segments which were then assigned to an existing category or a new category was created. In creating categories, I continually referred back to the research objectives to ensure the major categories were derived from them. Some text was not coded at all and some was assigned to several categories. Throughout the inductive analysis there was a continuing revision and refinement of the category system with subtopics to third level identified.

To further assess the trustworthiness of the data I undertook more consistency checks and sent the selected text segments and category descriptions to an academic at AUT, who suggested I had not immersed my self in the data significantly and that perhaps some of the categories had been imposed on the text. I had separated thepublic health experts and the smokers / ex-smokers into two groups but had used the same categories for both groups. I went back to the beginning of the inductive analysis process and identified categories and themes, some of which were similar to previous categories but others were different. Before summarising I sent the text segments and categories including lower level categories for another consistency check. It went to the same academic at AUT and to another academic at the University of Auckland, both withMPH qualifications. I did receive verbal feedback from the first academic who thought some of the text did not match the category descriptions and the second agreed with the category descriptions I

had developed and the assigning of text segments. I immersed my self in the data again, and made further changes.

A tree diagram listingthe main categories and sub-categories to three levels was created prior to the development of categories into a summary table. In the final analysis, the two ex-smokers were combined with the smokers, as not enough were interviewed to be able to add an extra perspective to the findings. Opposing views between public health experts and smokers were investigated but there were no discernable differences between the two groups. The development of a general summary table and four tables for each major category signalled the end of the inductive analysis of the qualitative data process.

CHAPTER 4
RESULTS

This chapter will describe the results of the qualitative research undertaken in chapter three. These will be presented in four parts. The acceptability of a de-nicotinisation of tobacco policy is described first, followed by a description of the transition to de-nicotinised cigarettes, then the potential impact of a de-nicotinisation of tobacco policy and finally, the advantages and disadvantages of significantly reducing nicotine in tobacco.

Five tables display sets of results including a general summary of findings. Commentary will be made about each set of results and include examples of text from the interviews. After each quote the respondents will be identified as smoker (S) or public health expert (PHE). The gender of the smoker will be identified as either FS for female smoker or MS for male smoker.

4.1 Overview

The general summary of findings are shown in Table 4.1 below. There was no overall public and political support for the introduction of a de-nicotinisation of tobacco policy in New Zealand but there are possibilities in the future. There would be significant barriers to introducing the policy. If the government did want to implement a de-nicotinisation policy it would need to prepare carefully and consider how it would promote a cigarette that was less hazardous. Other policy options were considered more acceptable including first, the sale of nicotine-free and nicotine cigarettes with differential taxation on nicotine and second, reduction of nicotine and tar but not to non-addictive levels. Alternative nicotine delivery systems (ANDS) should be made available for smokers to assist them to quit or reduce smoking. Strict regulation of nicotine in smoked tobacco and ANDS would be required to ensure tobacco industry compliance and to ensure more people were not encouraged into the market thinking the de-nicotinised cigarettes were a *safe* option.

Table 4.1: Summary of findings

Major categories	Description of major category
Acceptability of a de-nicotinisation of tobacco policy □ Public acceptability □ Political acceptability □ Barriers to introducing the p olicy	A de-nicotinisation of tobacco policy would have some support amongst the public but there could be a major backlash from smokers. The barriers could be insurmountable in the current political environment but may be overcome in the future. The government would probably also need to reduce the harmful constituents in cigarettes, simultaneously with the nicotine, for the cigarettes to be acceptable.
Transition to de-nicotinised cigarettes □ Prep aration for the transition - Promoting a less hazardous cigarette □ Policy options for implementation - Alternative policies - Use of alternative nicotine delivery systems (ANDS) □ Nicotine regulation requirements	Shifting smokers from nicotine to non-addictive cigarettes with the option of access to ANDS would require a combination of consultation and education with the public. De-nicotinisation could be introduced in stages. There could also be a policy which provides for a choice of nicotine and nicotine-free cigarettes using differential taxation on nicotine. Strict regulations would be required.
Potential impact of a de-nicotinisation of tobacco policy □ Health impact □ Social impact - Flow-on effects - Access to high nicotine cigarettes □ Economic impact - Cost / benefit to government □ International policy on de-nicotinisation	Policy makers would need to ensure they could manage the possible short term negative health impact on current smokers, while significantly imp roving future health. There could be social problems with some smokers turning to other drugs. The tobacco industry would be opposed to de-nicotinisation and fight the implementation of the policy.
Advantages and disadvantages of de-nicotinising tobacco □ Harm reduction strategy □ Potential and current smoker behaviour	The major advantage of de-nicotinisation of tobacco is reducing population harm caused by smoking but a disadvantage could be that the total harm could be increased if smokers compensated in their smoking b ehaviour to access more nicotine. Smokers would find it easier to quit smoking and young people who experimented with smoking would not become addicted to smoking.

The long term health imp act was likely to be p ositive but there was concern that there would be a negative health impact in the short term. Economically it was considered the tobacco industry and other tobacco retailers would be adversely affected but there would be new financial opportunities for the tobacco and pharmaceutical industries to develop new nicotine products. There would be enormous initial costs for the government but long term there would be a significant cost benefit.

There could be a social impact with smokers and their families not cop ing if the smokers could not access their usual levels of nicotine. Some 'key informants'11 thought there could be an increase in violence in the community, divorce rates could soar and smokers would feel frustrated and angry which could also lead to depression. There could be an increase in black market activity as smokers try to access nicotine cigarettes either through the black market or the internet which would be hard for the government to monitor.

A de-nicotinisation of tobacco policy would reduce population addiction to nicotine in smoked tobacco in the long term and assist those smokers who are already keen to quit smoking. The downside could be that more young people may experiment thinking de-nicotinised cigarettes are a *safer* option and more smokers may decide to either shift to nicotine in other products or use both cigarettes and ANDS rather than quitting smoking. There are pros and cons to de-nicotinisation of tobacco as a public health intervention.

4.2 Acceptability of a de-nicotinisation of tobacco policy

A range of views are presented in Table 4.2 which give an indication that it would not be very easy to gain public and political support for the introduction of a de-nicotinisation of tobacco policy. There were mixed views on the acceptability of a de-nicotinisation of tobacco policy with some people having negative and some positive views ofthepolicy. There probably would be some support, particularly from smokers who would like to quit

'key informants'- refers to 'public health experts' (including 'government officials', 'politicians', 'academics', 'health reporters' and a 'tobacco control advocate') and 'smokers' (including ex-smokers) who were interviewed by the researcher.

smoking but some would be extremely angry and it is likely there would be a backlash if this policy were introduced in the present social and political environment. **Table 4.2: Acceptability of a de-nicotinisation policy**

Label for category	Key characteristics	Text examples
Public acceptability	Negative	'..there would be strong opposition from the smokers and the tobacco industry..' (PHE) 'There are some screwed up people dependent on cigarettes who are going to get angry.' (SF)
	Positive	'Good for smokers who want to quit.' (SF) '..I would think the evidence is likely to be best in terms of not recruiting young smokers and the public tends to be very sympathetic to the needs of children.' (PHE)
Political acceptability	Not acceptable	'I don't think it would ever be politically tenable.. the outcry from smokers would be enormous.' (PHE) 'They [smokers] would be extremely resentful that the drug was taken out of their drug of choice. So there would be political implications for that which would probably prevent it goingthrough in the first place.' (PHE)
	Conditional	'… electoral acceptability? I guess there would have to be a phased reduction...' (PHE) 'smokers' acceptability goes without say ing...if smokers aren't going to switch to it, then really that's a big issue, in terms of p olicy.' (PHE)
	Potential acceptability	'I think it's worthy of some exploration. I think that if others are doing it, that's fine. Let's have a look and see how it comes out.' (PHE) 'I like the idea but I do recognise that you would have to do it carefully..'(PHE)
Barriers to introducing the policy	Strong opposition	'I think a lot of people would be unhappy ..at least half would be really kicking up a stink.' (SF) 'I think there would be quite a bit of animosity towards it. I think that people would be quite obstructive around it..'(PHE)
	Social prohibition	'It flies against pretty much everything else in society which is liberalisation of most social prohibitions.' (PHE) '... .this is taking away the freedom of choice.' (SM)
	Harmful constituents remain	'Why would they want to do it, when what they are doing is actually taking out the non-harmful part of the cigarette...'(SM) 'If non nicotine cigarettes induce smokers to smoke more then more people will suffer from artery problems, heart attacks...' (SM)

The freedom of choice issue came up with most of the 'key informants', many of whom believed that if the government did not offer smokers a choice of nicotine cigarettes that they would be behaving in a *big brother* way. Nicotine is a legal drug and therefore most believed that smokers had a right to access it. Most 'smokers' would either quit smoking or their delivery device of choice would be cigarettes which give a *hit* of nicotine, unlike nicotine replacement therapy (NRT) and other smoking cessation aids presently on the market.

The politicians were more enthusiastic about the political acceptability of a de-nicotinisation of tobacco policy than many other 'key informants'. There would be a number of barriers to introducing a de-nicotinisation of tobacco policy, which would probably be difficult for the government to overcome in the current environment. The barriers the government would be likely to face are in particular:

- ? Strong opp osition from the smokers.
- ? The policy could be considered social prohibition.
- ? The harmful constituents would still be in the cigarettes.

Public acceptability

Generally there was more negativity about the public acceptability of de-nicotinisation of tobacco but there was limited support for it.

Strong opposition from smokers: Most people thought there would be a backlash of some kind, to a de-nicotinisation of tobacco plan, from many smokers and the tobacco industry. 7 *think there would be a huge backlash from smokers. From a solid core of smokers' who would defend their right to smoke to the bitter end.'* (PHE)

> '.. *itwouldbe the thin edge of the wedge as far as they [the tobacco industry] are concerned unless it was happening all over the world... I just think it would be very, very politically risky.'* (PHE)

'I can anticipate the kind of battles that you would run with the tobacco industry, given that cigarettes are a legal product.' (PHE)

Smokers would become angry: It could be difficult for smokers who are addicted to nicotine to cope. They may become angry.

7 think a lot of people would be unhappy.at least half would be really kicking up a stink.' (SF)

'If people are using cigarettes to get through stressful moments what are we going to do to get through stressful moments.' (SF)

Positive

Easier for smokers to quit: Most people thought it would be good for smokers who wanted to quit smoking.

'..I *think for a lot of people it would be their good chance to give up because there are so many smokers who want to give up and can't for various reasons.'* (SF)

' ...it would certainly make it easier to give up, for those who wan ted to give up.' (PHE)

Young people would not be recruited: It has thepotential to significantly reduce addiction among young people, which would probably appeal to the public.

'*.. you would expect that the risk of getting young kids addicted to nicotine at a very early age there would be a kind of harm reduction approach by reducing nicotine would potentially reduce the harm to young kids*.' (PHE)

'*. .young people starting out on smoking, maybe 13,14,15 perhaps if the cigarettes contained no or very little nicotine then the ability of the habit of the cigarette to addict them long term might be weakened...'* (PHE)

Political acceptability

Most 'key informants' did not believe it would be acceptable yet but some thought perhaps it would be in a few years. Generally, most people thought it would be a very brave government who introduced a de-nicotinisation of tobacco policy.

Not acceptable

Politically risky policy: The opposition from smokers would be enormous which would be a concern to government.

> *'Ijust think it would be very, very politically risky.'* (PHE)

> 7 *think there would be quite a bit of animosity towards it. I think that people would be quite obstructive around it, smokers who had been smoking for a while.'* (PHE)

> *' ....the politi cal reality is that I can't imagin e it getting through…'* (PHE)

A pretty radical step: A lot of smokers would want to continue accessing nicotine via cigarettes and would be resentful about the significant reduction of nicotine in tobacco, which would have political implications.

> *'It's a pretty radical step to enforce, you're actually forcing people to give up the drug. Really it's enforced abstinence because you're removing the drug from the product... Boy I can imagine the furore over the freedom of expression.'* (PHE)

Conditional

Slow phase in of reduction: If the voters considered the policy acceptable, then it is possible, it could be introduced. The nicotine would probably need to be phased out gradually.

> *'...you wouldn't notice over 28 months* [suggested timeframe in interview] *it would be such a minute amount every month that's going out that you wouldn't know.'* (SM)

'..the slow weaning off strategy is going to be kinder to individuals' (PHE)

Do something whether you want to or not: Some key informants thought if smokers were supportive of de-nicotinisation of tobacco the policy could be implemented but others were not happy about the policy being mandatory under any circumstances. *'Nicotine-free cigarettes wouldprobably be popular.'* (SF)

'..you're actually having to do something whether you want to or not.' (SF)

Potential ac ceptab ili ty

Worth exploring: Some people thought it was worthwhile scoping what was happening internationally.

'*... see what we can get in ternationally and bring it in to New Zealand and be at the leading edge of policy on it.'* (PHE)

'*... another strategy is those international forums and if you can get movement there first then that's an ideal way to trigger something domestically.'* (PHE)

Implementation is possible: It could be politically acceptable provided it is planned and implemented very carefully.

'They have to do a number of things and it would have to be a variety of things in order to try and make a successful attempt a t making this work, like the introduction of different products and programmes and perhaps subsidies for various coping things.' (SF)

7 *think if the government was prepared to sit down and have a really good look at this and quite frankly they should, but maybe not look at nicotine patches and that. Maybe look at newer drugs that are coming onto the market that, not like Prozac or anything but...'* (SM)

Barriers to introducing the policy

The main barrier for the government is acceptability. Unless de-nicotinisation of tobacco is acceptable to the public and particularly smokers there would be too much opposition for a government to consider it. There would be implications for their future politically.

Strong opposition

A lot would be unhappy: Most key informants thought there would be quite a number of people who would not be happy about the policy and would oppose it.

> *'You would probably never get to that level [non-addictive] realistically because there would be a core group of people that would be so opposed to that occurring...*' (PHE)

> *'I reckon some [smokers] would be angry.'* (SF)

Social prohibi tion

Freedom of choice: Most people felt the policy would interfere with the rights of smokers. It could be considered that significantly reducing nicotine in tobacco is a type of social prohibition.

> *'Mandatorypolicy is 'big brother'.* (SF)

> *'If the Labour government put forward any further restrictions.... they already have a nasty image of being a bit of a nanny state and sort of telling people what they should and shouldn't do rather than letting them decide for themselves and I think you'd find that that flew in the face of freedom...'* (PHE)

> *'Well, what this is doing is taking away freedom of choice with legislation.'* (SM)

> 7 *should perhaps say I don't support a compulsory reduction, I support a choice.'* (SF)

Harmful constituents remain

Condoning the damage: Many of the smokers were concerned that the government would consider removing a relatively non-harmful constituent but allow the harmful constituents to remain in the tobacco.

> *'What they're doing at the moment is saying "oh we're not going to have people addicted but those that are smoking, we're saying don't kill your self" but we're actually condoning it, we're condoning the damage that people are doing to themselves by leaving the tar in and taking the nicotine out.'* (SM)

4.3 Transition from nicotine to de-nicotinised cigarettes

If the government was interested in moving from nicotine to de-nicotinised cigarettes the transition would have to be very carefully planned to gain the full support and cooperation from the public and the public health sector as shown in Table 4.3. The preparation would need to include research and policy analysis before a final decision was made by a government to implement a de-nicotinisation of tobacco policy. In planningthe introduction of a de-nicotinisation of tobacco policy, thepublic would need to be consulted and educated simultaneously to ensure they were *fully conversant* with all the issues surrounding the elimination of nicotine from tobacco.

A de-nicotinised cigarette is not *safe.* Thepublic need to be aware that the product will prevent addiction but if they continue to smoke the product it is just as dangerous as a nicotine cigarette. In implementing a de-nicotinisation of tobacco policy, the 'key informants' favoured a longtimeframe for reducing nicotine levels and thought support systems to assist smokers to manage their continued smoking, shift to ANDS or quit smoking would be needed.

Most people thought it would be necessary to offer a choice of nicotine and nicotine-free cigarettes and also that the harmful constituents should be reduced at the same time as nicotine. There was also reasonably strong support for slowly reducing nicotine and tar but not necessarily reducing nicotine to non-addictive levels. There was mixed support for ANDS. Most people believe the government should provide medicinal nicotine for

Table 4.3: Transition from nicotine to de-nicotinised cigarettes

Label for category	**Key characteristics**	Text **examples**
Preparation for the transition	Research and policy analysis	I think piloting it...'(SF) 'Needs properpolicy analysis.' (PHE)
	A blend of education and consultation	'There would need to be a lot of pre-education... '(PHE) 'I think they should have a referendum....' (PHE)
Promoting a less hazardous cigarette	Public to be informed	'.can legitimately argue pros and cons of it..' (PHE) '... spend a lot on advertising and education around [de-nicotinisation]..' (PHE)
	Consumers to be warned	'It still needs a warning, this is hazardous...' (PHE) '..the message that tobacco causes death and disease is much easier to market..' (PHE)
Policy options for implementation	Preference for longtimeframe	'.you would get a substantial quit rate..' (PHE) '.a long term phase reduction in nicotine content might overcome some consequences..' (PHE)
	Support systems for smokers	'Just have everythingto assist smokers ...' (SF) 'You could give them [heavy smokers who don't want to quit]some kind of licence to use..' (PHE)
Alternative policies	Provision of a choice	'I just don't know whether you'd get away with not giving a choice.' (PHE) 'That's where we go back to the tiered prices for the amount of nicotine in the cigarettes.' (SM)
	Reduce the harmful constituents	'You'd want to do that [reduce tar] to try and mitigate that health blip...' (PHE) '..there are things like just reducingthe tar, nicotine content of products [that could done now]..' (PHE)
Use of alternative nicotine delivery systems (ANDS)	Mixed support for ANDS	'Strongly advise the government to have some other form of nicotine, preferably for free.' (SF) '..I don't know if I would go along with other options for consuming nicotine...' (PHE)
	Mixed views on medicinal nicotine regulation	'..sensible for the government to look into looseningup laws around that [ANDS].' (PHE) '..[ANDS] be dealt with the same as the new designer drugs entering the markets.' (PHE)
Nicotine regulation requirements	Regulate timeframe	'.. force the manufacturers to reduce the nicotine fractionally....'(PHE) '..introduce regulations that gradually scaled it down..'(PHE)
	Develop strict testing regulations	'Tobacco industry would be subject to random testing...'(PHE) '..regulations are going to have to try and cover the tricks that the industry will use...' (PHE)

smokers if they want to quit smoking but do not necessarily consider nicotine in another p roduct as a useful adjunct to the p olicy. Strict regulation of nicotine would be the key to the success of a de-nicotinisation of tobacco policy.

Preparation for the transition

The government would need to prepare for the transition from nicotine to de-nicotinised cigarettes very carefully and not make any final decisions on the implementation until they had moved through the preparation stage.

Referendum and surveys: The government would need to consult with the public, particularly smokers and the smokefree workforce and find out their views on de-nicotinisation of tobacco.

> 7 *reckon they should do a survey first and ask all the smokers what do they think and you would sort of know iftheywere going to be really angry.'* (SF)

> *'I guess we would have to survey smokers as well. It's a pretty radical step to force.'* (PHE)

> *'..the most difficult one* [component of de-nicotinisation of tobacco plan] *is to get buy in to it, to get some form of agreement amongst New Zealand, particularly New Zealand smokers to do it.'* (PHE)

A blend of education and consultation

Education prior to preparation: Most people thought there would need to be a major education campaign prior to the introduction of the policy. The public would need to be believe it was an effective method of reducing population harm caused by smoking. *'You have to educate people so widely.'* (PHE)

> *'Say about the benefits of the low nicotine cigarettes compared to the high nicotine cigarettes. Let people know all about that.'* (SM)

'..educate the benefits, if there is such a thing, of low nicotine or no nicotine cigarettes to younger peop le. (SF)

Research and policy analysis

Research needed: It would need to be well researched before being introduced.

'Need to research peoples' habits and behaviours associated with cigarettes and social activities and any gathering of people atapub..' (SM)

Properpolicy analysis required: Some 'government officials' believed there had not been enough policy analysis to make any decisions on a de-nicotinisation of tobacco policy. *'There's always going to be the argument around the quality of evidence that supports this kind of policy and the problem is actually how you get the evidence that is of sufficient quality to win the kind of arguments you need to win.* ' (PHE)

Promoting a less hazardous cigarette

Consumers need to be provided with comprehensive information on the de-nicotinisation process so they can make informed choices about how they will use the cigarettes at all stages of the process. The public need to be aware that the issue is not *black and white* and they need to be well informed to ensure they understand the de-nicotinisation of tobacco process.

Public needs to be informed

For and against: There are arguments for and against de-nicotinised cigarettes. The public needs to be fully informed.

'*... nicotine isn 't the damaging part of the cigarette so you would still ge t kids who were damaging their lungs because of inhaling cigarette smoke but if that wasn't going to be an ongoing phenomenon then you would think you would get a reduction in harm overall.'* (PHE)

Need to spend a lot on what this is doing: An education and advertising campaign would be required to explain the de-nicotinisation of tobacco process and the likely impact.

'You have to have some communication... A component for letting the public know.' (PHE)

' ...but have local smokefree officers or health promotion people informed enough so they can answer local questions but it's about informing the public and smokers about why it is happening.' (PHE)

Consumers need to be warned

Hazardous toyour health: Consumers will need to be warned de-nicotinised cigarettes will still be hazardous to their health even although the nicotine has been effectively removed.

'There would have to be clear messages about the harm cigarettes do on their

'*..there is a risk of a perception that the rest of the product* [without nicotine] *is* y..'(PHE)

Policy options for implementation

All the 'key informants' supported a long timeframe for the implementation of the de-nicotinisation process withplenty of support for smokers.

Preference for long timeframe

Slowly wean smokers: In the longterm smokers would probably quit smoking by reducing the nicotine levels in tobacco slowly.

'..you could phase it in so that the reduction isn't so noticeable. That's the way they get people offmethadonefor example.' (PHE)

If the nicotine in tobacco was reduced over a longperiod of time smokers might not experience withdrawal symptoms which could resolve some of the expected potential consequences.

'You would have to do it very slowly and put all the mechanisms in place to ensure those sort of things [unintended consequences] *didn't happen.'* (PHE)

Support systems for smokers

Smokers will need help: There will need to be a range of support options for smokers throughout the transition period from nicotine to de-nicotinised cigarettes.

> *'..like the introduction of different products and programmes and perhaps subsidies for various coping things.'* (SF)

> *'Free weight loss programmes.'* (SF)

> *'..itwouldbe good to have a variety* [of non tobacco nicotine products].' (SF)

Smokers' methadone: Nicotine treatment could be made available for very heavy smokers who could not or did not want to quit.

> *'And so if they're really that hooked they've really got a problem. They need smokers' methadone don't they, really?'* (PHE)

> *'Maybe do it, methadone maintenance. Ah, nicotine maintenance through GPs. It could be done there's a precedent. They're setting that up for methadone at the moment.'* (PHE)

Alternative policies

Alternative policies were suggested by some many of the key informants as preferred options.

Provision of a choice

Need to give a choice: Many of the key informants thought that it might be necessary to provide a choice of nicotine-free and nicotine cigarettes.

> *'I guess people will feel a little bit controlled. They won't have that choice.'* (SM)

> *'I suppose allowing them* [smokers] *access to full nicotine cigarettes for use not in public places. There would have to be specialised ghettos.'* (PHE)

Tiered prices for nicotine: Differential taxation on nicotine could be a useful method of encouraging smokers to smoke nicotine-free rather than nicotine cigarettes.

> *'You might have some very expensive nicotine tobacco around, like that costs 20 times more than the lower one, or something of this kind, tax it to hell.'* (PHE)

Reduce the harmful constituents

Really dangerous chemicals: The harmful constituents in tobacco could be reduced at the same time as the nicotine to try and reduce the harm caused to smokers who continue to smoke.

> *'..solving one problem doesn't cause the problem to go away but if they can manufacture a cigarette that has low or no nicotine then maybe they could manufacture a cigarette that doesn't have the other really, really dangerous chemicals in it.* ' (PHE)

It doesn't mean we can't do anything: In the meantime, the tar and nicotine could be reduced but not necessarily to non-addictive levels.

> 7 *can see the government lopping off the top end* [nicotine and tar levels].... ' (PHE)

Use of alternative nicotine delivery systems (ANDS)

Many of the key informants were not very enthusiastic about ANDS although there was some support for them. Smokers in particular were more interested in quitting smoking rather than shifting from one nicotine product to another.

Mixed support for ANDS

Have some other form of nicotine: Some 'key informants' strongly support the availability and accessibility of ANDS for smokers wishing to quit or reduce their smoking.

> *'If there was parallel provision and subsidisation of ANDS it would b e great because you'd basically get this huge, wealthy strong sector of the business*

community [pharmaceutical industry] *lining up with government and they'll walk all over the tobacco industry in countries like New Zealand.'* (PHE)

'.. and also a higher strength of them [ANDS]for *the really heavily addicted smokers... and I suppose there would be or there could be o ther products formulated all the time that would give people that needed a nicotine boostwhilst they're trying to hold off....'* (PHE)

Smokers won't go for them: Some key informants were not supportive of using ANDS.

[1]*… they'll just be addicted to that.* [AND S]' (SF)

'I would be surprised personally if it [ANDS] *worked.'* (PHE)

Mixed views on regulation

Loosening up of laws: Regulations should be slightly relaxed for nicotine in ANDS.

'Iguess the trick is to crank up the regulation on the tobacco rather than wind it back for the pharmaceutical stuff. I guess you can wind it back a bit.' (PHE)

Really tightly controlled: Regulations should be tough on nicotine in ANDS.

'Only if it [ANDS] *was really, really tightly controlled and only able to be accessed by people who had been smoking for like 30 years or more.'* (PHE)

Nicotine regulation requirements

Strict regulations would be required to ensure the tobacco industry complied with timeframe requirements. Independent testing of imported and domestic tobacco would be required. Regulation of nicotine in smoked tobacco would need to be strengthened considerably.

Regulate timeframe

Set timeframe in regulations: The tobacco industry would be required to reduce the nicotine levels in tobacco over a period of time by regulations.

'*.. they can have a lead in type of policy which would every six months or year, the levels of nicotine would drop, until they go to a point where there were none.'* (PHE)

Develop strict testing regulations

Tests on nicotine levels: The tobacco industry would be required to have their tobacco tested for nicotine levels.

'..you'd have to do testing... you'd have to be able to monitor the level of nicotine in cigarettes in case a rogue batch got through...' (PHE)

'. .at some stage there would be a standard set that cigarettes were not to have over x amount of nicotine then all the cigarettes would have to comply..' (PHE)

'*.. you're going to have to crank these nicotine levels back by the tests that we use way, way down to 10% of what we observe now and whatever tests we use the smoker may actually be getting say beneath the nicotine addictive threshold at that point.'* (PHE)

Tobacco industry tricks: Some public health experts thought the tobacco industry would probably attempt getting round regulations in some way so the government would need to be prepared to deal with any deviations they might come up with.

' ...the bioavailability of nicotine can be influenced by other constituents in the cigarettes and unless we know everything about it, we know more than the tobacco industry which undoubtedly we don't, we can'tfully cover that option...' (PHE)

'You would require the industry to report constituents in smoke. You would have to, before you did anything like that [reducing nicotine] *to activate proper disclosure and proper testing of the products so you knew exactly what was in the product before you started mucking round with the... '* (PHE)

4.4 Potential impact of a de-nicotinisation of tobacco policy

The impact of a de-nicotinisation of tobacco policy would largely depend on the preparation priorto the implementation of thepolicy. Table 4.4 shows thepotential impact could be far reaching and go beyond the health impact.

With a strong comprehensive tobacco control programme in support, there would be an increased likelihood of a positive population health impact in the long term. Although, if the uptake of smoking increased and smokers continued to smoke and smoked more intensively, the expected population health gain may not occur.

There maybe a short term health impact on current smokers who continue to smoke at the same rate. Smokers may indulge in compensatory smoking behaviour although it is not known for *how long* and *how much* they would compensate to maintain consistent nicotine levels.

One of the problems in assessingthe risk of introducing a de-nicotinisation of tobacco policy is quantifying it. There has not at this stage been enough research undertaken to be able quantify the risk and some 'public health experts' wonder if the quality of evidence would ever be robust enough to provide a definitive risk assessment. However, there are processes that could be put in place so that de-nicotinisation of tobacco could be an option when there is more evidence to support thepolicy.

There was concern that smokers would not cope with the de-nicotinisation of tobacco process and that would impact on them, their families and their community. Flow-on effects could include smokers turning to alternative risky behaviour if they could not access nicotine in their preferred *"delivery device"*. They could also look to access nicotine cigarettes through the black market.

Table 4.4: Potential impact of a de-nicotinisation policy

Label for category	**Key characteristics**	Text **examples**
Health impact	Negative	'..if you're goingto smoke more because you're not getting your fix, then you're goingto get more tar.' (SM) 'You are goingto have difficulty avoiding a health detriment blip...'(PHE)
	Positive	'..one of the objectives would be to reduce the number of people smoking..' (SF) 'Possibly less people would smoke, therefore could be health benefits for non-smokers as well.' (SM)
	Unsure	'..size of the risk and if that could be quantified.' (PHE) '.may not even be a health or amenity benefit..' (SF)
Social impact	Positive	'..all the movie theatres and everybody else would be able to take advantage of the extra cashflow.' (SM) 'You'd have more money to spend.' (SM)
	Negative	'Everyone would be so cranky. ..' (SF) '.there will be an illicit contraband kind of trade..' (PHE)
Flow-on effects	Turn to other risky behaviour	'..people with addictive personalities and then there is a risk they'll go to other drugs...' (SF) 'You might see an increase in marijuana smoking....' (SM)
	Nicotine cigarettes	'.. the ability to do that [bring in more potent cigarettes] in New Zealand is pretty easy.' (PHE)
Economic impact	Negative	'..less smokers would have an impact. ..' (SF) '..they'll [tobacco importers] say that their products have been banned..' (PHE)
	Increased opp ortunities	'.. the tobacco industry would go, in joint ventures, with the pharmaceutical industry.' (PHE) 'I think the pharmaceutical companies would be jump ing for j oy..' (PHE)
Cost / benefit to government	Cost	'..a revenue issue...' (PHE) '..fund all the support services for smokers.' (PHE)
	Benefit	'Reduction in medical services.' (SM) '..there would be less money spent on smoking related illnesses..' (PHE)
International policy on de-nicotinisation	Support if an international move	'.if they [WHO Technical Advisory Committee], can come up with even some consensus..' (PHE) 'If there was an international move ..' (PHE)
	Difficult to go alone	'..you'd need customs and tight border control.' (PHE) '.. this would be abig step..' (PHE)

There could be an negative economic impact for tobacco-related industries as there would probably be less smokers and tobacco companies exporting cigarettes to New Zealand would not want to comply with reducing nicotine levels. However there would also be increased opportunities for the tobacco and pharmaceutical industries to develop new ANDS and nicotine-free cigarettes. It would be costly for the government initially with a potential reduction in revenue and extra funding required for support systems for smokers. If there was a lead from overseas it could be worth New Zealand considering de-nicotinisation of tobacco, but would be difficult for New Zealand to implement this policy alone.

Health Impact

There should be a positive population health impact, particularly in the long term but there could also be a negative impact if the tobacco industry was not monitored and smokers were not supported throughout the transition to de-nicotinised cigarettes. The concerns are, in the main, the short term negative health impact. Smokers may compensate to maintain their supply of nicotine, causing increased harm per cigarette to themselves.

Negative

Increased health problems: There was concern that because the harmful constituents were not beingreduced the de-nicotinised cigarette would be just as harmful, if not more, as some smokers may smoke more to access the nicotine.

> *'People are still going to get lung cancer from smoking nicotine-free cigarettes.'* (SF)

> *'The health consequences of course if you just keep w inding back the nicotine they're probably going to get more tar and carbon monoxide and other baddies exposure by just compensatory smoking behaviour so you 'll actually get an increase in health effects...*' (PHE)

Positive

Reduce number of people smoking: Most people thought the policy would result in less smokers which would also provide health benefits for non-smokers.

> *'Possibly less people would smoke, like continue smoking, therefore could be health benefits for non-smokers andsmokers...*' (SM)

> *'I think it would be motivation to help them* [quit].' (SM)

> *'..obviously you don't get secondhand smoke issues. You endup with a healthier environment.'* (SF)

Unsure

Size of the risk: Many public health experts were not confident that there was enough evidence supp orting the introduction of de-nicotinisation of tobacco.

> *'I'm not convinced that we have sufficient evidence that we would do no harm.*'
> And...
> \.*sooner or later you've got to work on the best evidence and that's what I'm saying I guess but I don't think the best evidence is in yet.*' (PHE)

Social impact

The government would have to consider social issues if it was to introduce a de-nicotinisation of tobacco policy in New Zealand. There would probably be increased violence in the community and smokers trying to access nicotine cigarettes. However, there would be a financial gain for those smokers who quit or reduced smoking.

Positive

More money to spend: Individuals who had quit or reduced their smoking would have more money.

> '*... cost benefits of it for individuals.*' (SM)

Negative

Heaps of violence: Most people thought that smokers would have some difficulty coping with the reduction in nicotine, which could be an extra burden on local communities.

> *'Heaps of people will get aggro without that little bit of nicotine there. Imagine if everyone had no nicotine all of a sudden.'* (SF)

> *'Not only child abuse, also adult violence against women, divorce...'* (SF)

Increased black market: Most of the 'key informants' thought the black market would probably increase as smokers would be wishing to access high nicotine cigarettes.

> *'They'll get them from overseas. It may just mean that more people are bringing them through from overseas and there will be a black market created for those that want i t...' (SF)*

> *'..whether it would spark a black market, for example, if you basically remove nicotine pretty quickly and it was done on a local basis, in other words it wasn't an international move or even if it was actually, the potential for smuggling and black market nicotine products would be a risk.'* (PHE)

Flow-on effects

Smokers who were suffering from withdrawals from nicotine may look towards other drugs for their *hit* or they may look elsewhere to access nicotine cigarettes. Smuggling nicotine cigarettes would be likely to increase and would need to be controlled.

Turn to other risky behaviour

Move to other drugs: Most smokers thought that as the nicotine was reduced in tobacco there may be an increase in other drug use.

> *'..if they're not getting their kicks or jollies from that* [de-nicotinised cigarette] *they might go onto something stronger.'* (SF)

'..if the nicotine was not in the cigarettes then you've got to consider there's other things that people may pick up for example, smoke marijuana and stuff like that...' (SM)

Access to nicotine cigarettes

Control of nicotine cigarettes: Mechanisms would need to be put inplace to restrict the flow of nicotine cigarettes into New Zealand.

'. .you'd need customs and tight border control. (PHE)

'..you would have the likes of Columbia and a lot of places in South America etc. They would possibly bend to any pressure and so yes you'd probably be able to purchase from them but then you would have to have some pretty strong customs in the first place that would no tallow them to come in.' (SM)

Economic impact

The tobacco industry and retail outlets that sell tobacco would be likely to be economically affected with a predicted profit loss. However there could be commercial opportunities for thetobacco and pharmaceutical industries.

Negative

Less smokers would have an impact: If there were less smokers in the market, that would have a negative economic impact on the tobacco industry, tobacco retailers, dairies and supermarkets.

'..ifyou look at supermarkets and a lot of people make, like tobacconists for example, a living out of selling tobacco and lighters and stuff. I guess less people will be buying them if it's not addictive and less people w ill be smoking so they'll be losing their profit margin.' (SM)

'..ifyou're talking about lowering nicotine levels thatwill have an impact on their [tobacco industry] *business quite dramatically...'* (PHE)

Look at imported ones: Tobacco importers will also have to keep nicotine in their cigarettes at or below the required level.

> '*.. you 'd have to look at the imported ones, tha t they needed to have a level of nicotine for all cigarettes coming in...'* (PHE)

Increased opportunities

More varied nicotine replacement: Both the tobacco and pharmaceutical industry would probably be keen to develop ANDS, which were acceptable to smokers tryingto quit or reduce their smoking.

> *'Nicotine would not be the problem it's the tobacco itself so I would imagine the pharmaceutical and tobacco industry would spend a lot of effort to come up with products which weren't smoke delivered.* (PHE)

> '*... and I suppose there could be o ther products formulated all the time that would give people that needed nicotine boostwhilst they're trying to hold off. Science is moving all the time but there would probably have to be a lot more involvement in that field.'(PHE)*

> *'…* they'd [pharmaceutical industry] *see it as an opportunity for new markets wouldn't they?' (PHE)*

Cost / Benefit to Government

For the government there would probably be a cost benefit long term but there would be enormous initial costs. No government could embark on introducing this policy without the support of a very comprehensive tobacco control programme.

Cost

Revenue issue: Some people thought the government would be concerned about how they would replace the inevitable loss of revenue from taxation on tobacco.

> *' ....there's also the downside of where they're* [the government] *going to get the money from.'* (SM)

'They don't want us to give up, they'd lose too much revenue.' (SM)

Finding funds: The government would have to find extra funding to pay for support services for smokers.

> 7 *know there is not unlimited funds and it's just maybe looking at different ways. If weight is a problem then getting them* [ex-smokers] *involved in something like weightwatchers ...So I suppose looking at those sorts of things.'* (SF)

Benefit

Long term b enefit: M ost p eop le thought there would be a financial benefit to the government in the long term.

> '... *cost the government less in th e long run...'* (PHE)

International policy on de-nicotinisation of tobacco

There is research being undertaken internationally on the de-nicotinisation of tobacco and it is being well debated by 'international experts'. However, the World Health Organisation (WHO) has not developed a policy on de-nicotinisation of tobacco and to date no country has taken steps to implement the policy. A de-nicotinisation of tobacco policy in New Zealand would incur the wrath of the tobacco industry internationally and the government would have to be prepared to deal with that. If the WHO could set the direction it would be easier for New Zealand to introduce this policy.

More support if an international move

An international lead: If there was some agreement through WHO or an international body that could at least give some direction for countries to move forward on, it would help.

> *'I'm really keen to see what the WHO comes up with in their Technical Advisory Committee, like regulation and control.'*
>
> And...

7 *could imagine if there was a bit more clearer direction through the Framework Convention and it was over a bit longer period...'* (PHE)

Difficult if New Zealand goes alone

Need tight border control: Most people thought there would be increased smuggling and customs control would need to strengthened at our borders.

'..you're going to have trade, you're going to have black marketing, black market and smuggling of nicotine based products undoubtedly...' (PHE)

'.. *you might get a black market emerging because we'd probably be the only country in the world where this was....'* (PHE)

Would be a big step: New Zealand is a small country to take on a de-nicotinisation of tobacco policy alone.

'... *it's got to be a big country like the US that's got to lead out on this.'* (PHE)

4.5 Advantages and disadvantages of de-nicotinising tobacco

There are advantages and disadvantages of eliminating nicotine in tobacco. If there could be more of an assurance that there would be reduced population harm, a government may feel more confident about introducing a policy to reduce nicotine in tobacco to non-addictive levels. The difficulty with a de-nicotinisation of tobacco policy is that it would seem almost impossible to introduce it without incurring a negative health impact in the short term. Table 4.5 sets out below, the advantages and disadvantages of a de-nicotinisation p olicy.

There was generally a belief that in the short term there would be an increase in harm to current smokers but in the long term there would be a significant public health benefit through a reduction in death and disease caused by smoking. There was also uncertainty that the cigarette may be more harmful if the composition was changed or that the

Table 4.5: Advantages and disadvantages of the de-nicotinisation

Label for category	Key characteristics	Text examples
Harm reduction strategy	Reduction in population harm	I suppose it would stop a lot of illnesses and diseases in the long run...' (SF) 'The reasons for considering it [de-nicotinisation policy] I hope would be that this will reduce the harm that tobacco causes.' (PHE)
	Continued or increased population harm	'if you're going to smoke more because you're not getting your fix then you're going to get more tar, you're goingto get increased health problems..' (SM) '..they're [smokers] probably goingto get more tar, you're goingto get increased health problems.' (SM)
	Unsure	'.. by changing composition of products you've perhaps created a more harmful cigarette.' (PHE) 'You might reduce the number who smoke but the consumption goes up again.' (PHE)
Potential and current smoker behaviour	Advantages	'..I don't think removing nicotine from cigarettes would effect initiation . .but it makes an awful lot of sense when people get beyond that..' (PHE) '..people would find it easier to quit and wouldn't get hooked necessarily.' (PHE)
	Disadvantages	'It would be awful. You would have to take twice as big a drag to get the same kick.' (SF) '..you would smoke more.' (SM)
	Smokers could choose to smoke	'I would assume that they would say "well, look there we go, it's not as addictive, I can stop when I want to, I choose to smoke".' (PHE)
	Ex-smoker and non-smoker behaviour	'.amongst ex-smokers the risk of having one or two fags and then suddenly being hooked again is less if you've got lower nicotine content.' (PHE) 'I think you would get the same amount of people try ing smoking...' (SM)

number of smokers may decrease because consumption of tobacco may go up.

There is no doubt that a de-nicotinisation of tobacco policy could wean smokers off nicotine and ensure that new smokers would not become addicted to nicotine in tobacco. It would also make it easier for smokers who wanted to quit or reduce smoking to do so. Smokers could choose to smoke rather than be addicted to smoking and if ex-smokers did decide to have a cigarette they would not become addicted to smoking again.

Harm reduction strategy

There would probably be a reduction in population harm in the long term but there may be a short-term increase in harm to current smokers who continue smoking.

Reduction in population harm

Stop a lot of illnesses and diseases: Some people thought it could have the effect of reducing death and disease in the future.

> '. *.you've got to look at the health factor. Even if people reduce, cut down that are heavy smokers, that's a good start isn 't it?'* (SF)

> '.. *positive things would be obviously people would be in better health.'* (SF)

Continued or increased population harm

Health effects of weaning process: If smokers smoke more because they cannot access enough nicotine to get their *fix* then there is likely to be an increase in health problems.

> *'..they* [current smokers] *don't want to be weaned off in such a patronising manner so that is where the real problem is, health effects of that...'* (PHE)

> *'..you* [smokers]allgeta *bullet of health damage in the first two-thirds of the programme until you get down to nicotine levels which are beneath the addictive threshold..:* (PHE)

Mixed views

Benefit to some but not to others: There is thepotential to be successful in weaning many smokers off nicotine in tobacco but the harm per cigarette continues for existing smokers.

'..there would be subsidiary views about the well-being of long term addicted smokers but I think that would be secondary to the long term public health benefit.' (PHE)

> '.. *first from a principle of "do no harm ", does it have the potential to cause any sort of unforeseen problems...'* (PHE)

Potential and current smoker behaviour

More or the same number of young smokers may experiment with smoking because they perceive it to be a safe option but they are likely to, not continue smoking if they do not become addicted. Current smokers may take advantage of being weaned off nicotine and quit smoking. They may also indulge in compensatory smoking behaviour during the process of the reduction of nicotine in their cigarettes.

Advantages

Less likelihood of becoming addicted: Everyone interviewed thought that *new* smokers would not become addicted to nicotine.

> *'...in terms of behavioural change of the masses, this kind of approach has probably got more potential then attempts to change individual behaviour ...you would get a whole generation of young people who w er en't given the opportunity to become addicted..'* (PHE)

> *'...there would be less likelihood of them becoming addicted.'* (SF)

> *'Young smokers, probably the consumption rate would drop because there wouldn't be that addiction....'* (PHE)

Would find it easier to stop smoking: Smokers would probably find it easier quit smoking if they were weaned off the nicotine in cigarettes.

> *'I would like to think that they would be able to stop like that...'* (SM)

> *'..I think for a lot of people it would be their good chance to give up..ifthey found the nicotine wasn't there to draw them maybe they'd give up...'* (SF)

> 7 *think it would be motivation to help them* [quit]' (SM)

Disadvantages

Smoke more: Smokers would smoke more cigarettes to access more nicotine.

'..it increases your smoking again because it's the same effect as smoking mild cigarettes.' (SM)

More or the same number of people smoking

Might get more people starting: Mixed views on whether more people would smoke or not.

'*.. you get a bigger popula tion of kids exp erim enting and deciding they like it..'* (PHE)

'The problem with it is that you might get a lot more people starting.. ' (PHE)

Smokers could choose to smoke

Smoke because they want to: Smokers would not have to smoke if they did not want to. They could choose because they would not be addicted.

'..it is beneficial, a smoker is going to smoke, so if they can smoke a safer cigarette than what they are, they might choose to do that.' (SM)

'If they were just smoking because it was something they wanted to do, I suppose it would drop[consumption of tobacco] *but not immediately.'* (PHE)

Ex-smoker andnon smoker behaviour

Suddenly being hooked again is less likely: Most people thought ex-smokers would not be tempted back into the market to smoke but a few thought they would take up smoking again because it is not addictive.

'I've had so many ex-smokers tell me that they took it up again after one cigarette.. It's obviously an addiction which is difficult to shake. And it seems to me this would assist.' (PHE)

'..if they pick up another cigarette and it's not addictive and they know it's not going to be so much of a risk...' (PHE)

Mixed views on non-smokers taking up smoking

Same amount of people trying it: Some people thought more young people would try smoking because it is not addictive, others thought there would be about the same number or fewer people.

> *'...in terms of young people and their uptake of cigarette smoking, theoretically it would reduce the number of young people who thought they would try it..'* (PHE)

> *'..the downside of that harm minimisation approach may well be that you get more kids experimenting because they know it's not going to be addictive...'* (PHE)

4.6 Conclusion

The results of the qualitative research show that there is generally a lack of support for a de-nicotinisation of tobacco policy to be introduced in New Zealand particularly, 'without the demonstrated effectiveness in other countries'. However, there is support for the government to add a harm reduction approach as part of a comprehensive tobacco control programme.

Many 'smokers' were not happy that they are addicted to smoking and would be very supportive of the government making it easier for them to quit smoking. However, most felt the de-nicotinisation of tobacco option was a little too *draconian* and were concerned they would be unable to cope with the reducing levels of nicotine.

Most of the 'public health experts' thought the government should consider variations of the de-nicotinisation of tobacco policy. There was concern about the lack of quality evidence to support the introduction of this policy and in particular the anticipated negative short-term health impact of current smokers. Although it was generally acknowledged there would be a significant reduction in population addiction. Smokers who did not want to quit smoking would be the most disadvantaged by the elimination of nicotine in their cigarettes and their health would need to be managed very carefully.

As a starting point, there was support for more research and consultation with the public health community, including health professionals and public health workers, before considering a de-nicotinisation of tobacco policy. There was also support for beginning a process of lowering nicotine levels in cigarettes but not to a non-addictive level. This would need to be accompanied by a simultaneous reduction in the harmful constituent levels.

CHAPTER 5
DISCUSSION

This chapter provides discussion on the limitations of the methodology includingthe process of conducting the research and analysing the data. Tables 5.1- 5.4 describe the key issues of de-nicotinisation of tobacco from two aspects, one based on the 'research evidence'[19]12 and one based on interviews with 'key informants' as described in chapter three. Issues that emerge from the results of the qualitative research and the literature sources are also discussed and considered with a final summary of the main points.

5.1 Limitations of the methodology

The selected methodology to obtain the primary data was qualitative research. This method of research was abl e to p rovide the raw data which assisted in determining the acceptability of de-nicotinisation of tobacco as a policy in New Zealand. The methodology was validated by the richness of data accessed from the subjects in the research. However there were several difficulties in accessingthat data, particularly in the initial stages of the research.

One supervisor suggested I include a clinical trial as part of the research with smokers testing nicotine-free cigarettes. However, it was considered almost an impossibility within the timeframe and would have taken the study beyond the realms of a Master of Public Health (MPH). It is certainly a limitation that a clinical trial was not included.

Conducting the research

Timeframe was a major issue particularly when my initial recruitment plan for smokers and ex-smokers was unsuccessful. I spenttoo long preparing and planningto undertake the research before beginning the process of recruiting key informants to interview. I underestimated how long it would take to recruit and interview key informants and then transcribe and analyse the data.

Recruitment issues

There were no problems with recruitment of public health experts. They were easy to recruit as I knew them all except one who refused to be interviewed but redirected my request to a colleague of his who I did know. The other two who refused to be interviewed did so because of a conflict of interest. On the other hand, recruitment of smokers and ex-smokers, in particular, proved to be extremely difficult. In the end I was only able to interview two ex-smokers and they were the last two people to be interviewed. It was probably difficult because I was looking for ex-smokers who had quit smoking for at least six months but not quit for more than five years. I could have interviewed many ex-smokers who had quit for years.

In the recruitment plan, in consultation with my supervisors I had decided to interview focus groups of smokers and ex-smokers including a mix of male, female, Maori, non-Maori , young, old, blue and white collar workers. I thought it would be best to try and organise focus groups mainly through workplaces, local community and personal /work networks. However, the reality was that even with very supportive Chief Executive Officers (CE0s) and community networks, smokers ignored recruitment notices on staff noticeboards and an advertisement in a community paper. After advice from Velma McClellan (health researcher) I offered small rewards to any smokers prepared to form a focus group. This unfortunately did not make any difference.

I believe there was probably no response to the notices even with the lure of vouchers because of the impersonal nature of the notices and no contact between myself and the potential key informants. If I had been able to go to the companies and perhaps talk with smokers and ex-smokers, the outcome may have been different but I think it would have been difficult to persuade employers to agree to a more intrusive recruiting procedure. Ethical approval from the Ethics Committee may have also been difficult. I have also been informed by health researchers that market research companies have made it very difficult for students wishing to recruit subjects, as they are prepared to pay focus group

[12] 'Research evidence' refers to the evidence from the literature search.

participants very well, and even then they too have difficulty recruiting for focus groups13 . Many people are not prepared toparticipate in research unless they are well rewarded.

I also had a problem recruiting a Maori focus group. It could be argued that the Maori focus group did not occur because I did not give it sufficient priority to ensure that sufficient numbers were attracted and therefore would feel welcome. However, there were time pressures and it was not a problem specific to the recruitment of Maori interviewees, as there was a general lack of response to all initial attempts to organise any focus group interviews. It is acknowledged that there would have been better participation if this research was by Maori, with Maori and for Maori. In the past, Maori have participated in health research mainly as subjects which has lead to suspicion and a reluctance by many to be recruited into research (Te Manawa Hauora, 1992).

Conducting the interviews

I was only able to conduct one pilot interview with a public health expert. I was unable to organise a focus group of smokers and ex-smokers and I was under pressure with time. Following the pilot interview I made a few changes to the questionnaire. The main concern was the length of the questions, a couple were too long. I then rechecked the questionnaire for the smokers / ex-smokers and made a few changes as some of their questions were also too long.

There could have been limitations in the interviews I conducted with public health experts because I knew them all. Some I did not know very well but I had spoken to them all on at least one other occasion. Most of the interviews were conducted over a speaker phone which I think de-personalised them. In some cases that could be a limitation but I think it was useful as it kept the interviews very professional.

Conducting the interviews with the smokers and ex-smokers was sometimes quite difficult particularly in the workplace. Often time was limited whether it was in work

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According to National Research Bureau Ltd

time or duringthe lunch hour. During work hours participants wished to rush through the interview to return to work and if it was duringthe lunch hour they often wanted to rush through so they could have some relaxation before returning to work. Several interviews were undertaken in the *smoko* area of one workplace, which was in a semi enclosed noisy basement car park, where different smokers came and went.

Taping the interviews worked well except in the focus group situation. The notes taken for these particular interviews were very useful in filling in the gaps when the sound was inaudible. It was generally relatively easy to hear two or three participants on the tape but for the focus groups with four and seven participants, some were almost inaudible at times. I had to rely on my memory and notes taken. The first 15 interviews were taped on a borrowed tape recorder of high quality which unfortunately needed to be returned before I had completed all the interviews. I finished the remainder of the interviews with a tape recorder of slightly inferior quality which made it quite slow and laborious transcribing the interviews.

Bias in results of research

I was concerned when I was planning the research that results could be biased because participants may believe I was undertaking the research for ASH (action on smoking and health). Although I actually facilitated all the individual and focus group interviews myself, I believe I was able to conduct the interviews in an impartial manner. Only one participant from one of the focus groups commented on the fact that I was from ASH. She asked if I would be using the research for ASH but the question was more out of interest than any concern.

Data analysis

The general inductive approach to analy sethe qualitative data was a very time consuming but a thorough and effective method of developing generalised concepts. The data from the smokers and the public health experts provided the research with a depth of information that has assisted me in working towards determining the acceptability of de-nicotinisation of tobacco, the aim of the research. The combination of the data provided

by the smokers and public health experts has given a broad range of views using very different language but with some quite similar perspectives.

What would I do differently?

In retrospect, the first attempt to recruit smokers and ex-smokers was too ambitious for the timeframe. Next time I would begin recruiting and interviewing at least three months earlier than I did to allow for any problems that may occur. I would not attempt to recruit potential key informants through workplaces unless I could do it personally. When I employed a combination of convenience sampling and the snowballing technique to recruit subjects to be interviewed either individually or in a focus group, it happened very easily. I believe the difference was probably in the personal approach. It is very hard for people to refuse to be interviewed, when they are personally approached. Some of the contacts were through colleagues' partners and friends and others were through my personal and work networks. Smokers and ex-smokers often provided me with other names to contact following a group or individual interview.

I would not change anything about the process of recruiting and interviewing public health experts. Although I may be more inclined to request to interview participants on speaker phone even if they are in the same city, as the telephone interviews were more focused than the face-to-face and particularly easy to transcribe because the sound was very clear.

In future I would ensure I had a high quality tape recorder, particularly for interviewing focus groups. I would also prefer to use a facilitator for focus group interviews so I could take notes as well as tapethe interviews. However this could be difficult if usingthe convenience sampling and snowballing technique to recruit potential key informants, particularly for focus groups, as many occurred spontaneously. This method of samp ling would still probably be my preferred option. I would, in future, ensure that I contracted someone to transcribe all the interviews. Whilst it was interesting to transcribe some of the interviews it was a very tiring, time consuming activity and with timeframe pressures it would have been a better option to contract the work out.

5.2 What the 'research evidence' and the 'key informants' say

The gap between what the 'research evidence' says and what the 'key informants' say is not great. The research evidence is more technical and there is obviously a higher degree of understanding of the issues amongthe 'international experts', but there is a similarity in many of the themes from both groups.

Convergence of the 'research evidence' and the 'key informants'

There is a convergence of the 'research evidence' and 'key informant' opinions in relation to addiction, quitting, the appropriate timeframe to de-nicotinise cigarettes, research, consumption of tobacco, non-smokers coming into the market and population health gain. The 'international experts' and 'key informants were in agreement that it is probable that future smokers could be prevented from becoming addicted to nicotine in tobacco and current smokers could be weaned off nicotine in tobacco. It would probably be easier for smokers to quit smoking but some smokers who may have otherwise quit may decide not to because they perceive the product to be *safer.* Some smokers may use alternative nicotine delivery systems (ANDS) in combination or shift to ANDS to access nicotine.

A longtimeframe to move through the de-nicotinisation process is most acceptable but a short timeframe would probably ensure there would be no increased harm due to compensatory smoking. Research is required prior and during implementation of de-nicotinisation of tobacco. The consumption of tobacco should be significantly reduced; and there is the potential for significant population health gains in the longterm.

Divergence of the 'research evidence' and the 'key informants'

There is some divergence on the role of ANDS, compensatory smoking, increased harm, provision of a choice of nicotine and nicotine-free cigarettes, smoker acceptability of de-nicotinised cigarettes and unintended consequences of the de-nicotinisation of tobacco process. The 'key informants' were generally not very interested in the role of ANDS in the de-nicotinisation process, whereas most 'international experts' who are in favour of de-nicotinisation of tobacco and believe ANDS will play a crucial role, to the extent of even possibly avoiding compensatory smoking (Henningfield et al., 1998; Warner et al.,

1997). Most 'key informants' believe there will be some compensatory smoking in the short term. However some believe the increased harm could be mitigated by reducing the timeframe of the process and / or reducingthe levels of tar at the same time as the nicotine and using ANDS. There were mixed views on compensatory smoking among the 'international experts' and the 'key informants'. Most 'key informants' thought the increased harm would only be temporary but some thought it would be long term.

Most of the 'international experts' believe the policy has to be mandatory to be effective (Henningfield et al., 1998). However, a proposal has been put forward for discussion in New Zealand which promotes the sale of nicotine-free and nicotine cigarettes (Laugesen, 2001b). Many of the 'key informants' believe there would be too much of a backlash if the policy did not provide a choice, at least initially.

There are mixed views among both groups on smoker acceptability of de-nicotinised cigarettes. It is generally thought that de-nicotinised cigarettes would not be acceptable to smokers, given the lack of interest in nicotine-free cigarettes on the open market (in direct competition with nicotine cigarettes) in the past, for example, Merit De-Nic, Benson & Hedges De-Nic and Next (Gross et al., 1997). Some 'smokers' indicated de-nicotinised cigarettes may well be acceptable particularly to those wishingto quit smoking.

Smokers have not been able to access nicotine-free cigarettes in New Zealand. There is no reason to suspect that smokers, from the United States of America (USA) or other countries that have marketed nicotine-free cigarettes, would have a different view on how satisfying these cigarettes would be. Although New Zealand cigarettes do have higher levels of nicotine in them than many other countries includingUSA and Canada (Blakely et al., 1997) which could make nicotine-free cigarettes even less satisfyingto smokers here. Clinical trials would need to be undertaken with New Zealand smokers to determine their actual acceptability of de-nicotinised cigarettes. If clinical trials with de-nicotinised cigarettes in New Zealand produced a similar response to trials overseas which generally found that they were satisfactory but not as satisfactory as nicotine cigarettes (Butschky

et al., 1995) and 80% of the current 600,000 smokers did want to quit smoking, that would indicate that there could be a reasonable level of public acceptability. At any given time there are between 40-80% of smokers who want to quit smoking (Gray, 2001).

There is an expectation there will be unintended consequences, for example, an increased black market, increased access to cigarettes through the internet and social problems due to withdrawal of nicotine. However there was a mix of views among the 'international experts' and the 'key informants'. Some thought there was a possibility there would be no unintended consequences with complementary and supportive research (Henningfield et al., 1998) and a 'key informant' thought that reducing nicotine over a longperiod of time might overcome some of the potential unintended consequences by reducingthe demand for smoking.

The 'politicians' were all interested in de-nicotinisation of tobacco but could not see it being acceptable in the present climate. They could change their mind on this, if there appeared to be *electoral acceptability* particularly *smoker acceptability.* If there was public support, particularly smoker support, it could be politically acceptable. There are some possibilities for the future. Political and social acceptability is key to the implementation of de-nicotinisation of tobacco. Further New Zealand based research is the key to this policy gaining political acceptability.

Table 5.1 describes acceptability issues of de-nicotinisation of tobacco. A de-nicotinisation of tobacco policy was too complex for most people to seriously consider. There was support and interest from some public health experts and smokers but it was reserved and it was acknowledged that it could be very difficult for many *addicted or dependent* smokers to cope with such a policy.

There is still a lack of consensus on tobacco product regulation among 'international experts'. Until there is consensus among them it will be difficult for the government to

Table 5.1: Acceptability of de-nicotinisation

What the 'research evidence' says	What the 'key informants' say
Smoker acceptability of de-nicotinisation	
The marketability of a non-addictive tobacco product is thought to be low (Henningfield et al., 1998;Kessler, 1994; Stratton et al., 2001) but there is evidence that de-nicotinised cigarettes can produce smoking satisfaction to a similar extent as nicotine-containing cigarettes (Brauer et al., 2001). If the timeframe was too short in working through the de-nicotinisation process i.e. three days, it would probably not be acceptable to the smoker (Laugesen, 2001a).	Most people felt that smoker acceptability was essential for de-nicotinisation to be successful. One 'smoker' thought nicotine-free cigarettes would be popular. Most people thought smokers who were wanting to quit smoking would probably be quite pleased as it would help them quit. Others thought there needed to be a choice of nicotine-free and nicotine cigarettes. A lot of smokers would probably search out nicotine cigarettes through the internet or on the black market. 'Smokers' who were not particularly addicted were fairly indifferent about whether the nicotine was in the cigarettes or not. They smoked for other reasons. All the 'smokers' would prefer a long timeframe for de-nicotinisation of tobacco.
Political acceptability	
Primary barriers appear to be political and social (Henningfield et al., 1998).	Not acceptable in the present political climate. Could be, if electoral acceptability. May be in the future, if there is an international lead and all support systems for smokers are in place.
Public acceptability	
Three day timeframe for reducing the nicotine in tobacco would probably betoo short forthepublic (Laugesen, 2001a) Long timeframe would be more acceptable.	There is mixed public acceptability but generally it is thought there would be a backlash particularly from smokers and that without providing a choice of nicotine and nicotine-free it would probably not be acceptable.

develop a pathway forward (Blakely & Bates, 1998). The New Zealand government is interested in tobacco product regulation and to date, the Ministry of Health has undertaken a literature review to inform policy and development (Blakely & Bates, 1998) and reviewed policies of other jurisdictions (Bates, 1992). Recommendations were made to the Ministry of Health to achieve gradual and incremental reductions of tar and nicotine levels and to consider de-nicotinisation of tobacco as an option along with other harm reduction options and in the meantime keep a watching brief on international developments (Blakely & Bates, 1998). Other'government officials' and'politicians' supported this. One 'government official' thought the government could begin preparing for tobacco product regulations for tobacco product disclosure of ingredients. This could

then be *cranked up* in the future. The present supplementary order paper (SOP) to the Smoke-free Environments (Enhanced Protection) Amendment Bill (SFE Bill) and Smoke-free Environments Act 1990 (SFEA) before the Health Select Committee at present contains regulation makingpowers for tobacco product disclosure.

Regulations would need to be developed to reduce tar and nicotine and the Ministry of Health already has the power to do that under the SFEA. It could also be brought about by a voluntary agreement with the tobacco industry or taxation (Blakely & Bates, 1998). A major concern with a de-nicotinisation of tobacco policy for government officials is that all health policy is viewed initially from a principle of *do no harm* and tobacco control is viewed as a *no smoking* policy. De-nicotinisation of tobacco does not fit with this perspective.

A cost/benefit analysis would need to take place. One 'government official' thought it could probably work out if a significant number of the smoking population quit smoking. It really depends on the size of the smoking population that would quit smoking, the size of the risk and whether it was quantifiable. One of the major problems is the uncertainty that surrounds a de-nicotinisation of tobacco policy. One 'government official' thought the evidence would be difficult to gather. However another 'government official' did mention that if they worked on the basis of being absolutely certain about everything, they would never do anything.

Having a choice of nicotine and nicotine-free cigarettes is an issue that came up with the 'key informants'. A key concern 'international experts' have about providing a choice is weakening the outcome. If the aim of de-nicotinisation of tobacco is to prevent and significantly reduce addiction and encourage smokers to quit smoking then surely access to nicotine cigarettes would undermine that outcome. This strategy is supported by one tobacco product regulatory expert in New Zealand (Laugesen, 2001b) but it would be conditional on the use of differential taxation and restricted access to nicotine cigarettes.

The long timeframe for the implementation of a de-nicotinisation of tobacco policy has the support of the 'key informants' and the 'international experts' but it is acknowledged that it could cause increased harm per cigarette to the smoker who would probably compensate for more nicotine. Compensatory smoking behaviour is a very key area of concern and is the downside of de-nicotinisation of tobacco. This is where the strategy of having nicotine and nicotine-free cigarettes on the market together has an advantage over de-nicotinisation. Compensatory behaviour would not occur because there would be no nicotine to access in the nicotine-free cigarettes. However for this policy to be a success there would have to be:

- Extremely strict regulations in place to ensure young people could only access nicotine-free cigarettes.
- An extensive quit campaign.
- Provision of subsidised ANDS to encourage smokers to shift from smoking.
- A closely monitored black market.
- A significant price difference between the nicotine and nicotine-free tobacco.
- Any packaging of the nicotine-free cigarettes would not be able to imply in any way that these cigarettes were *safer* to smoke.
- An extensive education and information campaign so the public were provided with the facts.

If the nicotine-free cigarettes were able to come on the market uncontrolled by government there would probably be an increase in smoking with more young people experimenting with smoking.

Table 5.2 below compares the 'research evidence' on the implementation of a de-nicotinisation of tobacco policy with the 'key informants' views. Thetimeframe for the de-nicotinisation process is possibly the most troubling part of thepolicy. However, it is

Table 5.2: Implementation of de-nicotinisation

What the 'research evidence' says	What the 'key informants' say
Timeframe for introducing de-nicotinisation	
De-nicotinisation over a number of years slowly would appear to have the most support (Benowitz & Henningfield, 1994; Borland, 1997; Henningfield et al., 1998). Timeframes ranging from 3 days (Rose & Behm, 1995) to 15 years have been suggested by different 'international experts' (Benowitz & Henningfield, 1994). A short timeframe is not generally supported (Shatenstein et al., 2001).	Most of the 'key informants'thought the timeframe should be over a long period of time. A 'health reporter' suggested the reduction should take place over the life-time of current smokers. However a 'tobacco control advocate' thought there would be a faster net health gain with a short timeframe for the introduction of nicotine-free cigarettes.
Regulation of nicotine	
There should be flexible but strong regulations which would regulate nicotine ensuring a gradation of control based on known potential harm (Borland & Scollo, 1999; Warner et al., 1997; Wilson, 2001).	There were mixed views on whether *'clean'* (non-smoked tobacco nicotine products) nicotine regulations should be relaxed but most people thought regulations should be strengthened for *'dirty'* (nicotine in smoked tobacco) nicotine.
Use of alternative nicotine delivery systems (ANDS)	
Strong support for ANDS in parallel with de-nicotinisation. ANDS will assist smokers wishing to quit, reduce, *top up* on nicotine from another product or move to ANDS short or long term (Henningfield et al., 1998).	Mixed support for ANDS. Some people thought they were unnecessary, another addiction, extra expense. Some were supportive particularly of extra strength ANDS for those smokers who are heavily addicted to nicotine and cannot or do not want to quit smoking.
Choice of nicotine and nicotine-free cigarettes	
De-nicotinisation needs to be mandatory (Bates, 1992; Henningfield et al, 1998). A discussion document in New Zealand is recommending a choice of nicotine-free and nicotine cigarettes (Laugesen, 2001b).	Some 'public health experts' did not believe it would be successful if there was a choice of cigarettes. Many of the'smokers' thought there should be a choice of cigarettes on the market.
Research	
Complementary and supportive research is required to enable implementation of de-nicotinisation (Henningfield et al., 1998).	Research is required prior, during and following the de-nicotinisation of tobacco process.
Support systems for smokers	
Strengthening the treatment infrastructure is an important component of de-nicotinisation of tobacco (Henningfield et al., 1998).	Smokers would need an enormous amount of support to get them through the process. Some 'key informants' believe there is already a good treatment infrastructure with quitline.

agreed by many that if the policy were to be introduced and was carefully planned some of the concerns could probably be managed.

Many of the barriers appear insurmountable in the present environment but some could be resolved with more research and evidence which would either ensure that de-nicotinisation did not occur because it would be likely to increase the population harm of New Zealanders or that it would apositive step towards significantly reducing death and disease caused by smoking.

Table 5.3 below describes the barriers including enticement of a bigger population of young people to experiment with smoking, smokers encouraged not to quit and increasing harm per cigarette to smokers (duringthe de-nicotinisation process).

The main reason for considering de-nicotinisation of tobacco is, it would probably significantly reduce population harm caused by smoking in the long term. There should be less smokers and theoretically they would smoke only because they choseto smoke, not because they were addicted to nicotine. Many of those smokers would probably also smoke fewer cigarettes. There should be health benefits for smokers and non-smokers who would be exposed to less secondhand smoke.

Table 5.3: Barriers tode-nicotinisation

What the 'research evidence' says	What the 'key informants' say
Barriers	
New smokers may come into the market	
May be more attractive to inexperienced smokers (Blakely & Bates, 1998; Wilson, 2001).	More young people might experiment and decide they like smoking.
May **not quit smoking**	
Smokers may not quit smoking but move to alternative nicotine delivery systems (ANDS) (Blakely & Bates, 1998). Some smokers have previously shifted to light and ultralight cigarettes instead of quitting smoking (Stratton et al., 2001).	Smokers may not quit but move to ANDS or continue smoking and use ANDS. Smokers may also perceive the cigarette is safer and continue smoking.
Increased harm	
Some believe a short term negative health impact on smokers would precede a positive population health impact (Jarvis & Bates, 1999). The gradual timeframe for the reduction of nicotine could increase the harm per smoker over a longer period of time (Blakely & Bates, 1998).	Most thought there would be an increase in harm p er smoker in the short term. A few thought more smokers may take up smokingbecause it could be perceived as being a *safer* cigarette.
Compensatory smoking	
Compensatory smoking is a potential concern (Henningfield et al., 1998). If appropriate medical interventions are available a gradual timeframe could be managed (Henningfield et al., 1998). Compensatory smoking could be temporary (Scherer, 1999). Below the threshold of addiction compensatory smoking would probably not occur. Not all experts share this view (Jarvis & Bates, 1999). It may bepossibleto avoid compensatory smoking by provision of (ANDS) (Henningfield et al., 1998; Warner et al., 1997).	Most people were concerned compensation would occur. An academic thought that there would probably be an increase in harm per smoker from compensatory smoking but thought this may be able to be mitigated (not completely) by reducing the tar at the same time.

Unfortunately there are risks with this policy, there could be an increase in harm for smokers who try to access more nicotine from their cigarettes. Table 5.4 describes the likely impact of de-nicotinisation of tobacco. The prevention of addiction among new smokers provides the strongest case for de-nicotinisation of tobacco in terms of support from the public. Whilst there is not empirical evidence that prevention of addiction would

be the outcome there is almost universal agreement among the 'international experts' that addiction would be prevented (Henningfield et al., 1998; Stratton et al., 2001).

Table 5.4: Impact of de-nicotinisation policy

What the 'science' says	**What the 'key informants'** says
Quitting smoking	
Would probably make it easier for smokers to quit smoking (Zeller, 2000a).	Would probably be easier for smokers to quit smoking.
Addiction	
Would probably make the product non-addictive (Zeller, 2000a), prevent addiction (Stratton et al., 2001) and reduce the number of addicted smokers(Benowitz & Henningfield, 1994).	New smokers would probably not become addicted and current smokers would be weaned off the nicotine which would reduce the number of addicted smokers.
Consumption of tobacco	
Consumption of tobacco would probably be significantly reduced (Benowitz & Henningfield, 1994; Zeller, 2000a).	Most thought the consumption of tobacco would drop.
Reduction in population harm	
Smokers would probably smoke fewer cigarettes therefore there would be a significant reduction in harm per smoker (Benowitz & Henningfield, 1994; Zeller, 2000a) Cigarettes would be non-addictive and therefore reduce the burden of tobacco caused disease (Henningfield et al., 1998).	Most believed fewer people would smoke therefore there would be a reduction overall in population harm to smokers and non-smokers, particularly in the long term.

Whilst there has not been acceptance of de-nicotinisation of tobacco there has been acceptance of variations of the policy, for example, reducingtar and nicotine levels very slowly, providing a choice of nicotine and nicotine-free cigarettes at least initially. If these steps were taken to introduce a type of partial de-nicotinisation it would almost be inevitable that eventually de-nicotinisation of tobacco would happen without it ever being discussed or planned but just as a matter of course. The European Union (EU) have already embarked on this course of action by limiting the levels of tar and nicotine in the cigarettes available for sale.

5.3 Summary points

? The methodology was limited in that it only addressed theoretical acceptability of de-nicotinisation of tobacco. It did not address actual acceptability of de-nicotinised cigarettes. A clinical trial with smokers and nicotine-free cigarettes would provide actual acceptability of the de-nicotinised cigarettes by New Zealand smokers.

? Smokers and ex-smokers are difficult to recruit particularly for focus group interviews. This view was supported by a market research company which also has difficulty despite offering generous remuneration.

? Further research, particularly New Zealand based research is required as the evidence is not yet of sufficient quality for a government to feel confident in gaining public support for the implementation of a de-nicotinisation of tobacco policy.

? Lack of consensus by 'international experts' and lack of knowledge of the issues of de-nicotinisation of tobacco as a policy could mean that the tobacco industry will again take a leading role in controlling the promotion of risk-reducing products which would again probably result in no reduction in population harm.

? There are still too many questions that remain unanswered but harm reduction strategies can be implemented to prepare the way for more significant changes in the future when there is more evidence available.

? Can a government really not take any action at all when significant changes to a product combined with strict regulatory controls and a comprehensive tobacco control programme have the potential to significantly reduce population addiction and population harm caused by smoking?

5.4 Concluding comments

There is a lack of consensus among the experts in the field and also incomplete, sometimes conflicting scientific evidence (Blakely & Bates, 1998) which is also reflected in the 'key informant' interviews. Potentially there are significant health gains to be made by the introduction of a de-nicotinisation of tobacco policy but there are also very legitimate concerns, which may not be able to be sufficiently addressed.

This research went some way toward addressing some of the concerns of de-nicotinisation of tobacco but further research is required. There is some convergence and some divergence amongthe 'international experts' and the 'key informants'. The prevention of addiction in the future has an enormous amount of appeal to both groups. The potential health gains for future generations would also be significant. The concern is for the current smokers, particularly those that will continue smoking. This is a policy that would probably increase the harm to them in the short term. This is not a policy a government could introduce lightly. The key would be ensuring current smokers health is managed to ensure their continued smoking does not increase harm to them.

It would seem then as the problems for de-nicotinisation appear insurmountable at present that variations on de-nicotinisation are beginning to be considered as realistic options. The 'international experts' are particularly concerned about the need to develop effective p olicy both internationally and domestically. Lack of time available is a real concern. The tobacco industry is already researching and developing *less hazardous* products. Smokers are generally unaware of this activity.

More discussion on the key issues will need to continue to progress de-nicotinisation of tobacco or some other form of population harm reduction.

CHAPTER 6
CONCLUSION

The aim of this thesis was to determine the acceptability of introducing a p olicy of harm reduction in tobacco use in New Zealand involving reducing nicotine in tobacco to a non-addictive level. The aim has been achieved by exploring the issues around the likely acceptability, theprocess of implementation and thepotential impact of a de-nicotinisation of tobacco policy. The scientific evidence was studied and a range of views were sought from public health experts and smokers.

The purpose of the study was to build on international research and continue the debate on de-nicotinisation of tobacco amongNew Zealand public health experts and thepublic, particularly smokers. The ideal situation would be to explore the acceptabilility of a de-nicotinisation of tobacco policy internationally, however, that would be an enormous task. Realistically, an international policy on tobacco product regulation including reduction of nicotine and tar is unlikely, until the development of the Framework Convention of Tobacco Control (FCTC) has been completed in 2003. Even then it is unlikely the FCTC or the World Health Organisation (WHO) will take a leadership role in harm reduction and more specifically de-nicotinisation of tobacco (Laugesen, 2001a).

Whilst this thesis will not be able to answer many of the questions which remain unanswered, it has focused on an area that has not previously been researched or even seriously debated by the international experts in tobacco product regulation. There has been research on the acceptability of de-nicotinised cigarettes with smokers in clinical settings (Brauer et al., 2000; Butschky et al., 1995; Gross et al., 1997; Rose & Behm, 1995; Rusted et al., 1996) but there is no research to date, which investigates the likely public and political acceptability of a de-nicotinisation of tobacco policy.

6.1 Major conclusion

There is not enough consensus and scientific evidence to support the introduction of a de-nicotinisation of tobacco policy, nor would there be enough political and public support.

However there is support for New Zealand to contribute to the research effort internationally on the de-nicotinisation of tobacco. There is also support to monitor the situation internationally and take a lead from overseas research and debates regarding de-nicotinisation of tobacco.

Not enough support for de-nicotinisation

The government clearly would not enjoy sufficient support to introduce a de-nicotinisation of tobacco policy, in the present political and social environment. The major barriers to de-nicotinisation of tobacco appear to be political and social (Henningfield et al., 1998). According to 'key informants' this policy would be *'politically very, very risky'* and *'politically untenable'*. It would be *'a brave government that would take it on',* or *'a one term government'* and they would need to be *'strong enough to stick it out because there's going to be some flak'* and they *'would need to do a lot of public relations to sell it.'*

De-nicotinisation of tobacco would probably be unacceptable politically but there could be support for the policy in the future particularly if there was electoral support. If another country was prepared to develop a de-nicotinisation of tobacco policy then there is potential for political support but at present there are too many risks and not enough agreement among the international experts. Government officials may also be prepared to support thepolicy if there was some direction from WHO, particularly the FCTC.

There is limited support for de-nicotinisation of tobacco amongthe public health community who believe lowering nicotine in cigarette tobacco could lower the addiction risk, particularly for young people (Laugesen, 1999) and ex-smokers who could be tempted back into the market for an *occasional* cigarette without getting addicted (Blakely et al., 1997). Some of the 'government officials' thought *'the best evidence is not here yet'* and an 'academic' thought it would be crucial to have *'a strong ringing endorsement by the pub lic health group.'*

'Smokers' were mixed in their support for de-nicotinisation of tobacco. 'Smokers' who wanted to quit smoking or were not happy being addicted to smoking were quite supportive, as they thought it would make it easier for them to quit or reduce smoking. In the year 2000, high nicotine yield (>1.2 mg) brand variants tookthe top eight rankings on sales volumes in New Zealand (Laugesen, 2001c). This is an indication that smokers in New Zealand could be resistant to moves to significantly reduce levels of nicotine in their preferred cigarettes. This fits with responses from many of the 'smokers' who thought *'there would be strong opposition'* and *'at least half would be kicking up a stink'*. It would be crucial to have smokers' support if a de-nicotinisation of tobacco policy were to be introduced. The support among smokers could perhaps increase, if they thought the current high nicotine levels in New Zealand cigarettes were making it more difficult for them to quit smoking, especially those who wanted to quit.

6.2 Recommendations for the future

The following six recommendations have been identified from the results of the research and the literature review.

Recommendation 1: Research and monitor de-nicotinisation

Contribute to the research effort on de-nicotinisation of tobacco and monitor the situation internationally. The introduction of de-nicotinisation of tobacco as a policy would not be achievable without more international and New Zealand specific research. The government also needs to ensure it is up-to-date with the evidence that is emerging internationally. Government officials need to be contributing to the international debate. Research is needed on:

- Acceptability of alternative nicotine delivery systems (ANDS) from medicinal nicotine to recreation nicotine.
- Tobacco content including additives.
- Smokers' acceptability of the de-nicotinisation process and de-nicotinised cigarettes.
- Nicotine addiction.

- ? Numbers of smokers wishing to quit smoking and quitting behaviour of New Zealand smokers compared to smokers from other countries.
- ? Nicotine regulation.
- ? Tobacco product regulation.
- ? Commercial/trade impact.

TheMinistry of Health has shown a willingness to invest in research on population harm reduction strategies, including de-nicotinisation of tobacco, as a component of the national tobacco control programme. However some initial research was completed in 1998 and to date it has not been shared with the public health community.

The issue has not been given serious consideration in New Zealand but de-nicotinisation of tobacco could have significant population health gains for New Zealanders. By investing in research, valuable evidence would become available which would be useful for the government in their decision making on not just de-nicotinisation of tobacco as a policy but appropriate harm reduction strategies in the future.

Recommendation 2: Gradual reduction of nicotine and tar

Nicotine and tar levels should be gradually reduced and there should be an incremental and gradual reduction in the tar to nicotine ratio.

A global cigarette yielding 12 mgof tar and 1.0 mgof nicotine was proposed for adoption internationally by the year 2000 (Gray, 1996). It is now 2002 and New Zealand levels of nicotine and tar are still between 1.2-1.6 mgand 12-15 mg respectively. It is time to start reducingthese levels as New Zealand cigarettes are more addictive and more harmful per cigarette than many in other countries in the OECD.

There was support from many of the 'key informants' to begin a gradual reduction of tar and nicotine levels. The Environmental Institute of Scientific Research (ESR) have recommended to the Ministry of Health that nicotine and tar levels should be gradually reduced to those of North America, Europe and Australia and there should be an

incremental and gradual reduction in the tar to nicotine ratio. To be of any health benefit, a reduction in nicotine levels should be accompanied by at least the same proportionate reduction in tar [Blakely & Bates, 1998].

The government is considering reducing nicotine levels but to what extent has not yet been established. The Ministry of Health is presently preparing to develop the regulations to implement these reductions in the nicotine and tar levels in tobacco. There is enough research to support the process of reducing the level of nicotine and tar in tobacco. Whilst this is occurring there needs to be further research on how low these reductions should go. We could follow the example of Europe and the proposed global cigarette of limiting nicotine levels to 1 mgper cigarette (Blakely & Bates, 1998) or further to 0.9 mgper cigarette, which would still not induce compensatory smoking behaviour in smokers or we could move at a more radical pace and reduce the nicotine to non-addictive levels. Compensatory smoking will only occur below 0.9 mg and above 0.4mgnicotine(Laugesen, 1997).

The recommendation from the Institute of Environmental Science & Research Ltd (ESR) is to at least embark on a path *of moderate reductions* which would still leave open the possibility of dramatic reductions of nicotine levels in the future.

Recommendation 3: Research choice of nicotine and nicotine-free cigarettes

Debate and research the provision of a choice of nicotine and nicotine-free cigarettes on the market.

The debate on nicotine-free cigarettes coming onto the market needs to take place among the public health community and government officials simultaneously with research on:

- Behavioural aspects of New Zealand smokers.
- Differential taxation on nicotine.
- Nicotine and tobacco product regulation requirements.
- Access to nicotine and nicotine-free cigarettes.
- Nicotine-free cigarettes as cessation aids or tobacco products.
- Impact on the business/retail sector.

The discussion document circulating the public health sector on nicotine-free and nicotine cigarettes (Laugesen, 2001b) should be the basis for debate and discussion. It proposes restricting nicotine cigarettes for sale only through bottle stores, mail order or internet sales and p ermitting the sale of nicotine-free cigarettes through local tobacco retail outlets. Differential taxation on nicotine and access laws would be used to encourage consumers to switch to nicotine-free cigarettes.

Many of the 'key informants', particularly the 'smokers' would find a choice of nicotine-free cigarettes and nicotine cigarettes very acceptable. Freedom of choice was a major issue. Some 'smokers' would have been more supportive of de-nicotinisation of tobacco if a choice of nicotine and nicotine-free cigarettes were provided at least initially. Most 'key informants' thought smokers would support and welcome access to nicotine-free and nicotine cigarettes.

The advantage of consumers switching to nicotine-free cigarettes, without going through the de-nicotinisation process is they would not be at risk of increasing harm per cigarette to themselves. Smokers would not be induced to indulge in compensatory smoking behaviour because the nicotine level in the cigarettes would be below the threshold of addiction. In many way s this solves one of the barriers to the de-nicotinisation of tobacco process. However, consumers would have to be encouraged to switch to the nicotine-free cigarettes.

Omni Nicotine Free cigarettes could be on the market in New Zealand soon and this could provide an opportunity to put into practice some or all of the proposal which would provide for the sale of nicotine-free cigarettes at any retail outlets and nicotine cigarettes at restricted outlets. Preparations need to be made for the arrival of Omni Nicotine Free cigarettes, which are likely to be the first nicotine-free cigarettes on the market in New Zealand. British American Tobacco NZ (BAT), Imperial Tobacco and Philip Morris would probably be very quick to develop and market their own brands of nicotine-free cigarettes.

The Government has two choices before the nicotine-free cigarettes become available for sale in New Zealand :

- To plan and prepare to work up thepolicy in detail, commission the necessary surveys/research and launch a draft policy for consultation (Laugesen, 2001b). □ To do nothing and leave it up to the tobacco industry to control and promote the nicotine-free cigarettes, which would probably result in continued or even increased total harm to New Zealanders as has occurred with the tobacco industry controlling *light* and *mild* cigarettes.

Recommendation 4: Regulation of nicotine is needed urgently

Regulation of nicotine should be based on known potential harm. The more harm caused the more control required.

The regulation of nicotine in New Zealand should be urgently reviewed. Both the tobacco and pharmaceutical industries are beginning to develop new ANDS. There is a need to start distinguishing between the drug and the delivery vehicle (Sweanor, 1997) and to rectify the current imbalance in regulatory systems (Sweanor, 1995). At present there is an imbalance in the regulation of nicotine in tobacco, recreational nicotine and medicinal nicotine. The imbalance between *'clean'* and *'dirty'* nicotine needs to be resolved. The market for nicotine could be permitted in a way designed to favour the least harmful products (Sweanor, 1997). The problem is that tobacco is largely unregulated whilst medicinal nicotine is very strictly controlled. Recreational nicotine which is not generally used in New Zealand falls between the two pieces of legislation and is totally unregulated.

Many 'international experts' favour one nicotine regulation authority (Borland, 1997b). It is not essential but the division between hazardous and therapeutic nicotine needs to be well defined (Collishaw, 1997). The New Zealand government at least has the power to regulate nicotine in tobacco under the Smoke-free Environments Act 1990 (SFEA) and medicinal nicotine under the Medicines Act 1981.

Recommendation 5: Strict regulation of tobacco products

Development of strict regulations to control tobacco products and thetobacco industry.

Substantially intensifying control of the tobacco industry in New Zealand is required (Thomson & Wilson, 2002). Regulations must be developed to control the industry and tobacco products. Full disclosure of ingredients, brand by brand is required, additives should be banned, and packaging, promotion and distribution should be strictly controlled by the government. Independent testing of tobacco products is required to ensure the tobacco industry is complying with regulations. The ESR have made a recommendation to the Ministry of Health that a test could be developed that could measure the effective delivered nicotine content of a tobacco product (Fowles, 2001). This could lay the foundations for independent testing of nicotine levels in New Zealand.

The tobacco industry over they ears appear to have used a wide range of irresponsible means to maintain its profits (Thomson & Wilson, 2002). They have ensured their customers have remained nicotine dependent whilst they have had the knowledge to reduce nicotine content. They have resisted government attempts at regulation. Now, the government must overcome the considerable administrative and political barriers and use its legislative powers to control the tobacco industry.

The government does not have the luxury of making all the decisions on the direction that should be taken with risk-reducing tobacco products in the future. Events which it has no control over, will take over. The tobacco industry is aware of the debate and research on *less hazardous (safer* in tobacco industry speak) tobacco and is itself, already researching, trialling and test marketing *safer* tobacco products. Most governments are completely unprepared for this phenomenon.

The New Zealand government has the opportunity to take the initiative and prepare for the regulation of *less hazardous* cigarettes which may come onto the market in the near future. These cigarettes could be in the form of smoked tobacco or modified tobacco

products. They could be nicotine-free, with reduced toxins in the tobacco and smoke or both.

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APPENDIX 1

CONSENT FORM

CONSENT TO PARTICIPATE IN RESEARCH THIS CONSENT FORM WILL BE HELD FOR A PERIOD OF SIX YEARS

Title of Project: The Acceptability of the Reduction of Nicotine in Tobacco to Non-addictive Levels

Researcher: Trish Fraser

I have been given and have understood an explanation of this research project. I understand the discussion will relate to the reduction of nicotine to non-addictive levels in tobacco. I have had an opportunity to ask questions and have them answered. I understand that I may withdraw my self from the group at any time up to 31 August 2001.

I agree / do not agree to have the focus group meeting audio-taped.

I agree to take part in the research.

Signed:

Name:
(please print clearly)

Date:

APPROVED BY THE UNIVERSITY OF AUCKLAND HUMAN SUBJECTS ETHICS COMMITTEE on 13 September 2000 for a period of three years, from 13/9/00. Reference 2000/186

APPENDIX 2

THE ACCEPTABILITY OF THE REDUCTION OF NICOTINE IN TOBACCO TO NON-ADDICTIVE LEVELS

PARTICIPANT INFORMATION SHEET

To Participants

My name is Trish Fraser. I am a mature student at the University of Auckland enrolled for a Master of Public Health in the Division of Community Health. I am conducting research on *'The Acceptability of the Reduction of Nicotine in Tobacco to Non-addictive Levels'* as part of the Master of Public Health and have chosen this topic because I work for ASH. I am interested in the role of nicotine in the maintenance of smoking. The strategy of reducing nicotine in cigarettes to non-addictive levels has the potential to see smoking become a choice rather than a need.

You are invited to participate in my research and I would appreciate any assistance you can offer me. As part of my study I am meeting with groups of smokers and ex-smokers to investigate the acceptability of reducing levels of nicotine in cigarettes to non-addictive levels. I would like you to participate in a group meeting which will take about one hour. I would prefer to audiotapethe interview but this would only be done with group consent and could be turned off at any time. You may withdraw from the project up to 31 August 2001.

If you have volunteered to attend this group meeting as an employee within a company please be assured you have company approval to participate in this project.

All information you provide in the meeting is confidential and your name will not be used. You will be provided with a consent form to sign at the meeting.

Thank you very much for yourtime and help in makingthis study possible. If you have any queries or wish to know more please phone me at home (09) 378-4583 or write to me at:

Trish Fraser
ASH
PO Box 99-126
Newmarket
AUCKLAND

My supervisor is: Professor David Thomas
Director, Health Research Methods Advisory Service
Division of Community Health
The University of Auckland
Private Bag 92019
AUCKLAND

Tel: 373-7599 extn 5657

The Head of Division is: Associate Professor Rod Jackson
Division of Community Health
The University of Auckland
Private Bag 92019 AUCKLAND

Tel: 373-7599 extn 6343

For any queries regarding ethical concerns please contact:
The Chair, The University of Auckland Human Subjects Ethics Committee, The University of Auckland, Private Bag 92019, Auckland. Tel. 373-7599 extn 7830

APPROVED BY THE UNIVERSITY OF AUCKLAND HUMAN SUBJECTS ETHICS COMMITTEE on 13 September 2000 for a period of three years, from 13/9/00. Reference 2000/186.

APPENDIX 3

PARTICIPANT INFORMATION SHEET

Title: The Acceptability of the Reduction of Nicotine in Tobacco to Non-addictive Levels

To: CEO

My name is Trish Fraser. I am a student at the University of Auckland enrolled for a Master of Public Health in the Division of Community Health. I am conducting this research for the purpose of my thesis on 'The Acceptability of the Reduction of Nicotine in Tobacco to Non-addictive Levels' and have chosen this field because I work for ASH. I am interested in the role of nicotine in the maintenance of smoking. The strategy of reducing nicotine in cigarettes to non-addictive levels has the potential to see smoking become a choice rather than a need.

Your staff who smoke cigarettes are invited to participate in my research and I would appreciate any assistance you can offer me.

I would like them to participate in a focus group of smokers but they are under no obligation at all. Participation in the focus group will take between half an hour to three quarters of an hour and would preferably be during work time. I would prefer to audio tape the session but this would only be done with your staff's consent and could be turned off at any time or they can withdraw information up to 31 August 2001.

The names of your staff members will not be used and all information provided is confidential.

Thank you very much for yourtime and help in makingthis study possible. If you have any queries or wish to know more please phone me at home 378-4583 or write to me at:

Trish Fraser
ASH
PO Box 99126
Newmarket
AUCKLAND

My supervisor is:Professor David Thomas
Director, Health Research Methods Advisory Service
Division of Community Health
The University of Auckland
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APPROVED BY THE UNIVERSITY OF AUCKLAND HUMAN SUBJECTS ETHICS COMMITTEE on 13 September 2000 for a period of three years, from 13/9/00 Reference 2000/186.

APPENDIX 4

RESEARCH ON SMOKING FOR MASTER OF PUBLIC HEALTH THESIS

WANTED: Cigarette smokers (smoking more than one cigarette a day) and ex-smokers (quit smoking for more than 6 months and less than 5 years) to be interviewed for approximately 45 minutes.

If you are over 18 years and wish to participate in a group meeting on smoking, please contact Trish Fraser before 27 April 2001.

Trish Fraser
Student
Master of Public Health
University of Auckland
Auckland

Ph: (09) 378-4583 Mobile: 025-591-039 Email: frasers3@xtra.co.nz

APPENDIX 5

MAORI SMOKERS WANTED!

Maori cigarette smokers (smoking more than one cigarette a day) and ex-smokers (quit smoking for more than 6 months and less than 5 years) are wanted for a study on nicotine.

We need you to attend a group interview (on site) run by Marewa Glover, a Maori researcher & Trish Fraser, a student doing this research for her Masters of Public Health Thesis at University of Auckland.

The hui will take about 45 minutes and you'll get a $20 music, book or petrol voucher for your time. Kia ora!

If you are over 18 years and you can help us
please book in with Trish before 27 April 2001.

Phone TRISH on (09) 378-4583
or Mob: 025-591-039 or
email: frasers3@xtra.co.nz

or Marewa (09) 833-

8525

KIA ORA MO TO TAUTOKO KI A MAUA

APPENDIX 6

THE ACCEPTABILITY OF THE REDUCTION OF NICOTINE IN TOBACCO TO NON-ADDICTIVE LEVELS

PARTICIPANT INFORM ATION

To Participants

My name is Trish Fraser. I am at the University of Auckland enrolled for a Master of Public Health in the Division of Community Health. I am conducting research on *'The Acceptability of the Reduction of Nicotine in Tobacco to Non-addictive Levels'* as part of theMaster of Public Health course and have chosen this topic because I work for ASH. I am interested in the role of nicotine in the maintenance of smoking. The strategy of reducing nicotine in cigarettes to non-addictive levels has the potential to see smoking become a choice rather than a need.

You are invited to participate in my research and I would appreciate any assistance you can offer me. As part of my study I am interviewing approx. 5 government officials, 4 politicians, 4 media people, 2 academics/NGO people to investigate the acceptability of reducing levels of nicotine in cigarettes to non-addictive levels. I would like to interview you. The interview will take between half an hour to three quarters of an hour. I would prefer to audio tape the interview but this would only be done with your consent and can be turned off at any time. You may withdraw from the project up to 31 August 2001.

If you do wish to be interviewed please sign the attached consent form and sent it to me or phone me on Tel: (09) 378-4583 after hours. All information you provide in an interview is confidential and your name will not be used.

Thank you very much for your time and help in making the study possible. If you have any queries or wish to know more please phone me at home (09) 378-4583 or write to me at:

Trish Fraser
ASH
PO Box 99-126
Newmarket
AUCKLAND

My supervisor is:

Professor David Thomas
Director, Health Research Methods Advisory Service
Division of Community Health
The University of Auckland
Private Bag 92019
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The Head of Division is: Associate Professor Rod Jackson
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For any queries regarding ethical concerns please contact:

The Chair, The University of Auckland Human Subjects Ethics Committee, The University of Auckland, Private Bag 92019, Auckland. Tel: 373-7999 extn 7830.

APPROVED BY THE UNIVERSITY OF AUCKLAND HUMAN SUBJECTS ETHICS COMMITTEE on 13 September 2000 for a period of three years, from 13/9/00. Reference 2000/186.

APPENDIX 7

INTERVIEWS WITH SMOKERS' AND EX-SMOKERS'

Introduction

Firstly, I would like to thank you for being willing to take part in this group interview. My name is Trish Fraser, I am a student at the Department of Community Health, University of Auckland and I am interested in the reduction of tobacco consumption by gradually reducingthe nicotine levels to non-addictive levels in tobacco.

I have some questions written down but they are really just a guide. I want to hear what you have to say and there are no right or wrong answers.

Does anyone have any questions at this stage?

I would like to tape record what you have to say so that I don't miss any of it. I don't want to take the chance of relying on my notes or memory and thereby miss something that you say or inadvertently change your words somehow. So, if you don't mind, I'd very much like to use the recorder. If at any time during the interview you would like to have the tape recorder turned off just let me know and I'll turn it off.

I have a consent form for you to fill in and a Participant Information Sheet for you to read which I'll give you now. Could you take a few minutes to read the information sheet and sign the consent form to formally agree to participate in this group interview.

Questions for Group Interviews

Early Stage (setting the scene)

1. Can you tell me how you started smoking?[Smokers and Ex-smokers]

2. Have you made any attempts to stop smoking? [Smokers]

3. If yes] What difficulties did you have when you attempted to stop?[Smokers] [or stopped? Ex-smokers]

Middle Stage (key issues)

4. What do you think the key issues would be if nicotine was gradually reduced in tobacco to a non-addictive level?[Smokers and Ex-smokers]

Before we go any further I would like to share with you some of the key issues that have come out of the literature review I have undertaken. Perhaps you might like to consider these issues during the rest of this interview and think about whether they might be issues for us in New Zealand.*[Key issues that the smokers or ex-smokers did not speak about in the above question -prevention of adolescent addiction, easier to quit consumption, compensation, alternative nicotine delivery systems, black market, internet, mailorder, regulation]*

5. What do you think the issues for smokers could be?[Smokers and Ex-smokers]

**Would the taste of the cigarettes be affected?*
**How do you think a smokers' mood will be affected?[depression, irritability]*
**Whatdoyou think will happen with some smokers' behaviour ?[compensation] *What could smokers do to get their normal 'fix' ofnicotine?[ANDS] *Where would smokers get cigarettes with higher levels ofnicotine?[black market, internet, mailorder]*
**What would be the issues for smokers around the timeframe the government was going to work within to reduce the levels of nicotine to non-addictive levels in tobacco?[Pace of Reduction]*

6. If the government were to announce that they were goingto reduce levels of nicotine in tobacco to non-addictive levels how do you think they could do that in away that would be acceptable to smokers? [Smokers and Ex-smokers]

** What would you like to know about the policy?[information] *What timeframe do you think smokers could most easily cope with? *What sort of alternative nicotine products would you like to see available for smokers?*

7. Do you have any thoughts on what the impact of such a policy would be on smokers, ex-smokers and non-smokers?[Smokers and Ex-smokers]

**What do you think might happen to the health of smokers in the long term?[health gains]*
**Can you tell me what short term negative effect on h ealth migh t occur wi th the introduction of this policy?[compensation]*
**What do you think would happen w ith youth smoking?[reduction in uptake]*
**What do you think would happen to ex-smokers and non-smokers?[could encourage into the market]*
**What do you think the reaction would be to the government if they introduced this policy? [backlash]*

What would you as a smoker see as the advantages and disadvantages of significantly reducing levels of nicotine in cigarettes?[Smokers]

**What do you believe would happen to the death and disease rates caused by smoking?[long term reduction]*

**What are the advantages for smokers who are wishing to quit smoking?[easier]*

**What would happen financially to smokers who required more nicotine than was available in the cigarettes?*

Final Stage(more straightforward)

9. Doyouthinkthereis away of developing acceptable nicotine products thatwould satisfy smokers without subjecting them to the health risks they face smoking?[Smokers and Ex-smokers]

**What sort of involvement do you think the pharmaceutical and tobacco companies would have?*

**Whatdoyou think are the safety issues for a smoker who wants to permanently use nicotine in an alternative product to a cigarette?*

**What do you think the government can do to encourage research and development of alternative nicotine products?*

10. Could you tell me how ex-smokers might feel about less harmful nicotine products being available on the market which may encourage them to start using the products?[Ex-smokers]

**What temptations would there be for them to use alternative nicotine products?*

**Whatare the financial issues for ex-smokers?*

**What could be the problem for an ex-smoker taking up using an alternative nicotin e product? [anoth er addiction]*

11. How would you feel as a smoker having such a policy imposed on you. [Smoker]

12. Do you have any further questions or comments you would like to make before we finish this interview?[Smokers and Ex-Smokers]

Italics in boxes: Probes to deepen the response to a question. The theme which is expected to be covered as a result of the probe in brackets.

INDIVIDUAL INTERVIEWS WITH EXPERTS

Questions for Interviews Early Stage

1. Can you give me a bit of background information on the work you do, particularly in relation to tobacco control?

2. What do you think of the present tobacco control programme in New Zealand and its effectiveness?

Middle Stage

This thesis is looking at significantly reducing levels of nicotine in tobacco to non-addictive levels. This would take place in New Zealand and would need to be regulated to ensure all tobacco companies were reducing the levels of nicotine in their cigarettes over the same period of time. This policy has been well debated internationally and it appears most of the tobacco control experts who support de-nicotinisation of tobacco (the process) believe alternative nicotine delivery systems (ANDS) need to be available for those who are heavily addicted to nicotine. Smokers will try and get more nicotine from the cigarettes as the nicotine reduces.

3. So, what do y ou think the reasons would be for the government to consider introducing a significant nicotine reduction strategy?

4. What do you think their concerns and barriers to introducing a de-nicotinisation of tobacco policy would be?

5. What do y ou think the comp onents of a signifi cant nicotine redu ction strategy would need to be, to be successful?

6. How would the government go about marketing the concept of de-nicotinisation of tobacco to the public to ensure support?

7. What do you consider would be the best options for those smokers who are heavily addicted to nicotine and cannot or do not want to quit smoking?

8. What new regulations would need to be introduced to ensure a significant nicotine reduction policy provided a net health population benefit and not a net health population loss to the population?

9. How likely do you think it is that the government would take on a significant nicotine reduction policy and how would this 'fit' with international tobacco control strategies?

Final Stage

10. How doyou think the tobacco and pharmaceutical industries would respond to a de-nicotinisation of tobacco policy?

12. What are your thoughts in general about de-nicotinisation of tobacco and have you any further comments to add?

APPENDIX 8

Participant Profile

The following questionnaire is anonymous and is not compulsory to complete. I will be interviewing approximately smokers and ex-smokers including males, females, under 25 year olds, over 25 year olds, Maori, non-Maori, light and heavy smokers.

This brief questionnaire will ensure I have included abroad cross section of smokers and ex-smokers which will enable me to present unbiased findings from the interviews.

Please tick the appropriate box

1. Sex

Male

[

Female

Over 25 years

2. Age

Under 25 years

[

Non-Maori

Ex-Smoker

3. Ethnicity

Maori

[

4. Smoking Status

Smoker

[

Over 15 cigarettes per day [

Under 15 cigarettes per day [

Thank you.

Acknowledgements

Thanks to all the people who agreed to be interviewed.

Thanks to all the people who offered advice and support and special thanks to George Thomson, Marewa Glover, Velma McClellan, Bill Gruar and my supervisors Professor David Thomas and Dr Murray Laugesen.

Thanks to my family for their advice and support.