ASH Briefing paper

Harm reduction and the 'fully engaged' scenario

Summary

1. To achieve the 'fully engaged' scenario proposed by Wanless[1] requires Californian rates of smoking of around 17% to be reached in the UK by 2010. Once smokefree legislation has been introduced in summer 2007 the UK will have pulled all the known levers to cut smoking prevalence. However, even with the benefit of a 1.7% decline in population smoking due to smokefree legislation, a new strategy is needed because at current rates of change it is likely to still take us fifteen years to reach 17% smoking prevalence[2].

2. Smoking is the main avoidable cause of health inequalities, because the poor and deprived are more likely to be smokers, tend to smoke much more heavily, and find it much harder to give up. Therefore as overall smoking rates decline, health inequalities increase. Smoking rates amongst the poorest in society and those with serious mental illness for example, are above 70% compared to only 25% in the general population.

3. However, the public health goal is to reduce death and disease, not to reduce smoking prevalence as an end in itself. It's the tobacco smoke that kills people not the nicotine. It's the nicotine that people are addicted to and not the tobacco smoke. Currently tobacco smoke kills well over 100,000 people a year and half of all lifelong smokers die from diseases caused by their smoking.

4. Heavy taxation of smoking is an effective health measure to encourage people to give up. But this causes particular financial difficulties for poor and deprived smokers, so the Government also provides smoking cessation services to help people who want to give up. However, over 70% of smokers are not yet ready to quit[23] and this group is particularly concentrated amongst the most disadvantaged in society. The Government currently needs to do a lot more to help these smokers.

5. A harm reduction strategy is required which would give smokers access to less harmful forms of nicotine in a form and at a price that is attractive as an alternative to smoking. A switch of only 1% of the population a year from smoking to less harmful nicotine sources, a conservative target, would save around 60,000 lives[3] in only 10 years.

6. It would lead to reductions in morbidity as well as mortality, leading to significant immediate as well as longer-term savings to the health service. This would include, for example, reductions in time spent in hospital following operations[4],

[1] Wanless D. Securing Our Future Health: Taking A Long-Term View. HMT April 2002
[2] Jarvis M. Monitoring smoking prevalence in Britain in a timely fashion. Addiction 98, 1569-1574. November 2003
[3] Lewis S, Arnott D, Godfrey C, Britton J. Public health measures to reduce smoking prevalence in the UK: how many lives could be saved? Tobacco Control 2005;14:251-254
[4] Choosing Health: Making Healthy choices easier. Public Health White Paper. 16th November, 2004. Cm 6374.

fewer premature and low birth weight babies, and fewer heart attacks, strokes[5] , cases of respiratory disease and cancer. Achieving the 'fully engaged' scenario of smoking prevalence of 17% by 2010 would save hundreds of millions of pounds a year in NHS costs for stroke and acute myocardial infarctions alone[5].

7. Such a harm reduction strategy is practicable and there is evidence it would work. For example, Sweden is a country where consumers get their nicotine in different ways than in other countries. About as many men use smokeless tobacco as smoke. Swedish smokeless tobacco, known as snus, is much less harmful to health than smoking[6], but is banned elsewhere in the EU. Sweden has the lowest standardised rate of lung cancer incidence in the world, around half that of the UK[7], and much lower incidence of heart and lung disease as well.

8. The current system of regulation in the EU is illogical – tobacco is banned if it is designed to be sucked (as in the case of Swedish snus) but not if you smoke it or chew it[8]. There is no precedent for banning the less hazardous variant of a product and keeping the most dangerous on the market.

9. To implement an effective harm reduction strategy would require revision of the current regulatory system. What are needed are consistent single market rules that would regulate product standards and marketing for all non-smoked tobacco products, not simply legalise Swedish snus. The EU ban on snus is under review[9]. Until now the UK has supported the ban, the time has come for this support to be reassessed.

10. In contrast, medicinal nicotine is only licensed for smoking cessation, not for longer-term maintenance use. It is regulated in the UK by the Medicines and Healthcare Regulatory Authority (MHRA). The Secretary of State for Health and Chief Medical Officer could collaborate with the MHRA to produce an integrated approach to regulation of low harm nicotine products.

11. The HM Treasury could also play a crucial role in setting tax differentials between the newly licensed products and cigarettes using price to trigger behaviour change, particularly amongst poorer users.

12. Such a strategy would be a market-based, low-cost public health intervention. But it would require a strong political lead to be taken by Government.

13. It would encourage the development and sale of new, low harm nicotine products and ensure that all such products were subject to a common regulatory regime. This would give people the choice, not now available to them, to use products many hundreds, if not thousands, of times less hazardous than cigarettes, so saving lives and significantly reducing the costs of the health service.

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[5] Modelling the short term consequences of smoking cessation in England on the hospitalisation rates for acute myocardial infarction and stroke Bhash Naidoo, Warren Stevens and Klim McPherson Tob. Control 2000;9;397-400 doi:10.1136/tc.9.4.397

[6] Protecting smokers, saving lives: The case for a tobacco and nicotine regulatory authority Prepared by the Tobacco Advisory Group of the Royal College of Physicians, December 2002

[7] Source: WHO/IARC Cancer Mondial Database 2001 figure http://www-dep.iarc.fr/

[8] The ban was introduced in Council Directive 92/41/EEC (ban on oral tobacco) and is implemented in England by UK Statutory Instrument 1992 No 3134 as The Tobacco for Oral Use (Safety) Regulations 1992 to prevent the American product Skoal Bandits from entering the market prior to the advertising ban as there was concern it would be marketed to children. However, the advertising ban ensures marketing to underage and new users can be severely limited.

[9] This is reviewed every two years under Article 11 of Directive 2001/37/EC.

14. It would also support the introduction of smokefree legislation, help de-normalise smoking, significantly reduce exposure to passive smoke in the home where legislation cannot effectively intervene, and where children in particular are most heavily exposed, and help reduce the number of smoking-related fires in both domestic and commercial settings.

15. In taking forward such a strategy the Government would receive the full support of ASH and the Royal College of Physicians. ASH and the RCP will work to gain the support of other Royal Colleges of medicine, medical and scientific bodies.

Recommendations

16. Increase availability and accessibility of NRT in the run up to the introduction of smokefree legislation (these proposals fit well within the new DH public health initiative Small Change BIG DIFFERENCE):
    - ensuring that NRT is licensed for short-term use (known as temporary abstinence – the MHRA are currently looking at this and DH support will help ensure the licence is given)
    - ensure that NRT is available 24 hours a day in all outlets where tobacco is available – garages, 24 supermarkets etc. (again DH support is needed or this will not happen as retailers need to be encouraged to see it as part of their Corporate Social Responsibility); and
    - promote a smokefree homes (and cars) initiative in the run-up to the introduction of smokefree legislation with NRT prescribed to deal with cravings for those unable to give up smoking entirely.

17. The HM Treasury announcement on the 2007 Comprehensive Spending Review states that the Government is taking forward a programme of work involving: *'detailed studies of key areas where cross-cutting, innovative policy responses are required to meet these long-term challenges'.*[10]

18. Harm reduction and smoking prevalence is a good example of such a key area. Although accepted for some time in the areas of drugs and alcohol, it is not clear that Government has accepted the principle of harm reduction for smoking through the use of less harmful sources of nicotine. We would recommend that this principle be accepted.

19. The objective for the Government should therefore be the development of an integrated strategy for harm reduction and nicotine which would put this principle into practice. This would enable the PSA targets for the DH in the 2007 Comprehensive Spending Review to be tightened to match the targets in the 'fully engaged' scenario of 17% by 2010 with the downward trend continuing so that by 2022 smoking prevalence could be down to 11 per cent[1]. It would also enable the targets for reducing smoking prevalence among routine and manual groups to be made tougher, so reducing health inequalities.[11]

20. In particular DH should set up a working group including other relevant Government Departments such as HM Treasury, the MHRA, the Health Protection Agency, and public health stakeholders such as ASH and the RCP with terms of reference to include:
    - Defining a harm reduction strategy;

[10] http://www.hm-treasury.gov.uk/spending_review/spend_csr07/spend_csr07_index.cfm
[11] http://www.hm-treasury.gov.uk/media//70320/sr04_psa_ch3.pdf

- Determining what bodies are needed to implement a harm reduction strategy.

21. Key elements of the strategy would include:
    - encouraging the development of new low harm medicinal nicotine products for maintenance use;
    - ensuring that harm reduction and nicotine are key elements of the strategy flowing from the Drugs Futures 2025 Foresight Project;
    - the re-examination of the UK Government's policy position on the regulation of smokeless tobacco;
    - commissioning a literature review on smokeless tobacco to input into the next review of Article 11 of 2001/37/EC;
    - supporting the introduction of standards for Reduced Ignition Propensity (RIP) cigarettes under the EU General Product Safety Directive as a first step towards effective tobacco product regulation;
    - developing recommendations on what form regulation of all nicotine products should take in future, to ensure effective harm reduction;
    - commissioning work on the structure of a regulatory framework; and
    - determining what legislative changes might be necessary to implement a harm reduction strategy.

The harm caused by smoking

22. The purpose of reducing smoking prevalence is to reduce the burden of disease and death it causes, mostly from cancer, cardio-vascular disease and lung disease. One half of all lifelong smokers die prematurely from smoking related disease, half of these in middle age, losing from 5 to 25 years of life[12].

23. There is now substantial experience of medicinal nicotine. It is more than a 1,000 times safer than smoking and has only a few relatively minor negative effects on the health of adults such as a slight raising of blood pressure. However, currently clean nicotine is only available as an aid to giving up smoking.

24. Currently 26% of the adult population in UK smoke, around 12 million people, a figure that is declining by only 0.4% a year[2]. To achieve the 'fully engaged scenario' Wanless suggests that we need to reach Californian levels of smoking prevalence of around17%, which at current rates of change will take more than 20 years. Even if we were able to cut smoking prevalence rates to these levels there would still be about 7 million people smoking, half of whom would die from smoking-related diseases if they carried on smoking.

The impact of smoking prevalence on health inequalities

25. Reducing smoking is the only way the Government can meet its targets on reducing health inequalities as smoking is a major cause of health inequalities. It is the difference in rates of giving up smoking among different groups that has led to increasing health inequalities in the UK[13].

[12] Doll R, Peto R, Boreham J, Sutherland I, Mortality in relation to smoking: 50 years' observations on male British doctors BMJ 2004;328:1519
[13] Tackling Health Inequalities: A programme for Action Department of Health July 2003

26. There is a gradient in smoking prevalence with social class. In social class 1 around 15% of men and 14% of women smoke cigarettes[14]. In social class 5 smoking prevalence reaches 45% for men and 33% for women. Amongst men smoking accounts for over half the difference in risk of premature death between the social classes.

27. In consequence children in lower social classes are more exposed to tobacco smoke pollution which is a cause of cot death, the onset of asthma as well as asthma attacks, respiratory diseases and ear infections. 1.5 million children, one in seven, have asthma.

28. Amongst the most deprived groups smoking rates are particularly high. Studies of smoking rates among lone parents in receipt of social security benefits have found smoking levels in excess of 75%[15]. Smoking rates amongst Big Issue vendors have been found to be over 90%[16] and smoking prevalence among prisoners is estimated to be over 80%.[17]

29. There are also significantly higher smoking rates amongst those with mental health problems than amongst the general population. Studies have shown smoking rates to be as high as 80% amongst people with a diagnosis of schizophrenia and people with depression are more likely to smoke and have difficulty giving up.[18]

30. In the UK there are 8 million people with lung disease 2.1 million with angina, 1.3 million who have had a heart attack and 300,000 people who have had a stroke.[19] As smoking is a major cause of these illnesses a higher than average number of these people are smokers and many are currently are faced with the choice to quit or die. For example smokers who continue smoking after a heart attack are twice as likely to have another heart attack in the next year as those who give up.

31. There are an estimated 4.1 million adults with asthma in the UK with a smoking prevalence of 22%.[20] Smoking not only reduces lung function and triggers attacks among people with asthma, but also interacts with inhaled corticosteroids, the mainstay prophylactic treatment for asthma, in such away as to significantly reduce its efficacy.[21]

The use of price as a mechanism to encourage people to give up smoking

32. UK policy over the last ten years or more has been to increase the price of tobacco through tax rises. Genuine price increases do lead some smokers to quit and make very substantial health and welfare gains for those that do.

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[14] The data in this section is taken from smoking and health inequalities, a joint publication by ASH and the Health Development Agency
[15] Marsh A and McKay S (1994) Poor Smokers. London: Policy Studies Institute
[16] Big Issue (2002). Coming up from the Streets: What Big Issue Vendors Need to Escape Homelessness. Vendor Survey October 2002. Cardiff:The Big Issue Cymru
[17] Department of Health (2004) Choosing Health: Making Healthy Choices Easier. London: Department of Health
[18] McNeill A (2001) Smoking and Mental Health: a Review of the Literature. London: Smokefree London
[19] Towards smoke-free public places, British Medical Association 2003.
[20] *Where do we stand*, Asthma UK 2004
[21] Chalmers, et al *Thorax* 2002;57:226-230

33. However, tobacco is a highly addictive substance and so demand is inelastic, which means that more money is spent on tobacco after a price rise. It is currently estimated that a 10% increase in price leads to a 3% decline in consumption.

34. Therefore increases in tobacco tax are strongly regressive, hitting the poor hardest as they spend a disproportionately larger share of household income on cigarettes. The poorest tenth of the population spend 15% of their weekly income on cigarettes, compared to an average of 2% for the adult population as a whole. This is money that they cannot afford to lose. The cost of smoking 20 cigarettes a day is around £1700 a year for the most popular branded cigarettes.

35. The ethical dilemma of increasing the price of such an addictive substance has to date been addressed by making the greatest possible efforts to motivate and assist smokers to quit in response to the increases in prices.

36. Currently the Government spends around £50 million a year on stop smoking services. However, there is recognised to be a 'hardcore' of smokers who cannot or will not give up, and poorer, more deprived, smokers have more difficulty giving up than the better off, which is why health inequalities have increased.

Why poorer, more deprived smokers have more difficulty giving up

37. The underlying behavioural hypothesis, for which there is research evidence, is that tobacco use is a means of self administering nicotine, and that nicotine is addictive, causing the user to modify their behaviour to attain their desired nicotine 'hit'.

38. In 1998, 69% of smokers in England wanted to give up smoking. However, because it is an addiction it is difficult to give up. Only 5% of smokers making an attempt to quit succeed without help and even with support 80% of smokers making an attempt will fail in that attempt. Many will go on to make further attempts and eventually succeed but there will also be many who will be unable to overcome their addiction.

39. Those in lower socio-economic groups are just as motivated to quit as those in professional groups. However, rates of quitting are significantly lower amongst adults from the poorer social groups than amongst the better off. This is thought to be because the poor tend to be heavier smokers due, at least in part, to 'self-medicating' with nicotine to help them cope with the stress in their lives. Nicotine dependence is an important factor in the ease of quitting and there is good evidence from cotinine levels in the blood that poorer, and more deprived, smokers are more dependent on nicotine.

Harm reduction options for those who can't, or won't give up

40. It's the tobacco smoke that kills people not the nicotine. It's the nicotine that people are addicted to and not the tobacco smoke. Harm reduction strategies need to give people access to less harmful forms of nicotine. This will protect not just the smoker themselves but also passive smokers exposed to tobacco smoke pollution, including family members, friends and fellow workers.

41. This is a principle that has been accepted for many years in the area of illegal drugs, ever since needle exchanges were introduced to reduce the dangers of HIV infection amongst heroin users.

42. Yet this is still a subject of some debate in tobacco control circles. Some experts are still concerned that nicotine addiction is the main problem – deal with the nicotine drug use and harm reduction follows.

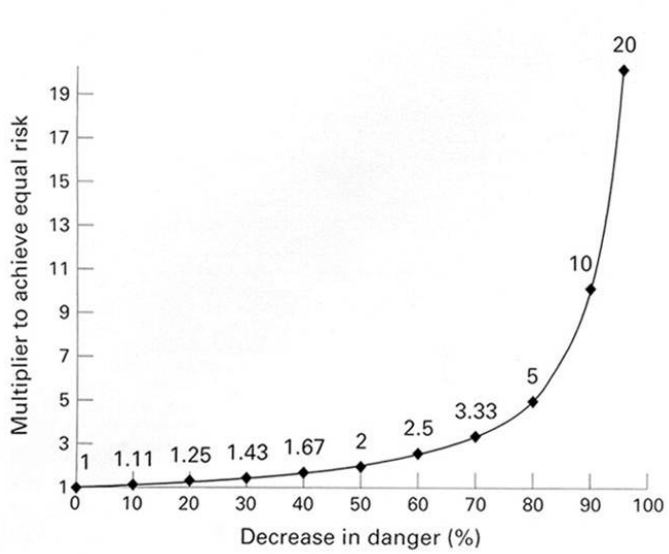
43. There are concerns that higher-dose nicotine products, were they available, might dissuade people from quitting and/or encourage the take up of nicotine amongst young people who would not have started smoking tobacco otherwise.

44. However, nicotine addiction has been around for hundreds of years and is likely to persist for the foreseeable future. It does not have the adverse societal effects that a drug such as alcohol can have, and, while more research needs to be done, there is some evidence that users are self dosing with nicotine because of beneficial effects that it can have on mood or concentration levels.

45. The graph below [22] shows the risk use equilibrium. If use of a product rises proportionately more than the risk, there is a net negative impact on public health. If use rises proportionately less than the risk declines, then there would be a net positive impact on public health. The graph shows the equilibrium line where there is no change in population level risks, as explained in the graph below.

46. There is a large body of evidence that nicotine itself is not a significant risk factor for cardio-vascular events, does not cause cancer, and does not cause respiratory diseases such as emphysema. Medicinal nicotine is much less harmful than smoking, certainly at least 1,000 times safer than cigarettes, which are very 'dirty' delivery systems for nicotine. Therefore, as the graph shows, its use can rise more than twenty times (an unfeasible increase) but would still cause much less death and disease than the current level of use of cigarettes.

Graph from Kozlowski[22], in Tobacco Control.



[22] Kozlowski LT, Strasser AA, Giovino GA, Erickson PA, Terza JV. (2001). Applying the risk/use equilibrium: use medicinal nicotine now for harm reduction. Tobacco Control. 10: 201-3.

47. The potential for reducing harm by reducing the toxins in smoke is not so great, offering risk reduction of perhaps a few per cent. Therefore the focus should be on harm reduction products which allow nicotine uptake through non-combustible means.

48. The current legal framework leaves the most dangerous form of tobacco use – cigarettes – the least regulated, while other less dangerous forms of nicotine products are subjected to heightened forms of regulation (medicinal nicotine) or outright bans (some forms of smokeless tobacco).

Current regulation of, and the market for, nicotine products

49. Nicotine products are produced by pharmaceutical companies and licensed as medicines by the Medicines and Healthcare Products Regulatory Agency. Currently the licence is only for use as stop smoking products.

50. In the Public Health White Paper *Choosing Health* states (p.138) that:
"The companies have publicly committed to look at new and innovative ways of making NRT more widely available. They are currently discussing with the Medicines and Healthcare Regulatory Agency (MHRA) the licensing restrictions around NRT, and are looking at wider access issues and other ways to promote the use of NRT, including:
    - *Raising awareness among healthcare and related professions by committing resource to that work;*
    - *New media campaigns;*
    - *Developing new and innovative therapies;*
    - *Promotion of therapies through a wider choice of outlets; and*
    - *Encouraging retailers to allocate more space for stop smoking therapy products and space alongside cigarettes."*

51. However, although nicotine products are on general sale, they are usually only available at pharmacists and big supermarket chains and certainly not in the wide variety of outlets where cigarettes can be bought, such as petrol stations, corner shops and newsagents.

52. Demand for NRT (over the counter as well as prescription) will rise dramatically in the months prior to smokefree legislation coming in, as was seen in Ireland and Scotland. This can be used as an incentive to encourage retailers to put NRT next to cigarettes, so that every time a smoker buys a packet of cigarettes the alternative, NRT, is available to them.

53. The profit margins are higher on NRT but retailers will still need to be encouraged to do so as an act of Corporate Social Responsibility as the turnover is much lower. DH could helpfully take the lead on this as the pharmaceutical companies have told us they have not found the retailers sympathetic to extending availability and accessibility. Links with retailers through Small Change BIG DIFFERENCE could be helpful here, and it would fit well within this public health initiative.

54. Furthermore, because they are such high margin products, despite the heavy taxation of cigarettes, the cost of using NRT is not much less than smoking and

there is insufficient price incentive to consumers to switch. This is exacerbated by the fact that medicinal nicotine is available currently from a far more limited range of outlets than cigarettes and therefore has to be bought in larger quantities to ensure continuation of supply. The pharmaceutical companies need to be encouraged to cut prices in the run-up to the legislation being introduced. Again there is a role here for the Department of Health.

55. Some helpful changes have taken place. The MHRA remit has changed to include *'making an effective contribution to public health….. and promoting the safe and effective use of drugs'.* The MHRA set up a working group to look at the licensing of NRT under this new remit. The MHRA has now recognised that the alternative for users of medicinal nicotine is to continue to smoke, which is far more harmful to their health, and its decisions about licensing of NRT are now guided by this principle.

56. The licence has now been extended to allow for cutting down tobacco consumption prior to quitting. Only 26% of UK smokers are ready to quit immediately, but a further 36% want to change their smoking but aren't ready to quit abruptly[23]. This new license now gives them that option. NRT has also been licensed for longer-term use up to 9 months and for pregnant smokers, young smokers from 12 to 17 and smokers with cardio-vascular disease.

57. Currently the MHRA are looking at licensing NRT for temporary abstinence, an indication that would help protect children in the home from parental smoking when their parents are unable to give up smoking completely. This fits well within the new public health initiative Small Change BIG DIFFERENCE and it would be helpful if DH were to support the implementation of this change in licence.

58. However, NRT is still not licensed as a harm reduction product for longer-term maintenance use and products are still not being produced by the pharmaceutical companies which would be suitable for such use.

59. Currently available forms of medicinal nicotine will not be able to attract a significant proportion of the 74% of smokers who are not interested in quitting now. Although NRT products are on general sale they are designed to minimise the risks of abuse and dependence and therefore do not offer most smokers a satisfying alternative to cigarettes. To do this would require the development of devices that deliver nicotine to the brain at a dose and rate similar to cigarettes, something that none of the currently available products achieves.

60. In the UK there are currently six different forms of medicinal nicotine delivery – gum, patch, nasal spray, inhalator, sublingual tablet and lozenge. The nicotine dose and speed of nicotine delivery vary between the products. The nasal spray has the fastest speed of delivery with nicotine peaking 10 minutes after a dose of spray and the patch the slowest with nicotine peaking after 4-9 hours of putting the patch on. Compare this to the cigarette where a concentrated dose of nicotine reaches the brain within 10 seconds of a puff[24].

61. But products competitive with cigarettes in speed of delivery are unlikely to be licensed under current medicinal guidelines, and therefore there is no incentive to manufacturers to develop them. Furthermore the pharmaceutical companies are

[23] Data on file – IPSOS Omnibus sample size 2860, UK April 2004
[24] Review of the Implementation of the Tobacco Product Regulation Directive 2001/37/EC McNeill A, Joossens L, Jarvis M. 2004

nervous of getting into this area unless they believe there is political support for such developments. Therefore the current regulation of nicotine as a medical therapy is a significant obstacle to the commercial development of new more attractive devices[25].

62. Hence the current regulatory framework ensures that new non-tobacco nicotine products, which could compete directly with tobacco, are unlikely to be developed and marketed widely and effectively guarantee the market for recreational nicotine to the most harmful delivery system, the cigarette.

Current regulation of smokeless tobacco products

63. Smokeless tobacco is from around 10 to 1,000 times less hazardous than smoking, depending on the product[26] [27]. However, currently one of the safest forms of smokeless tobacco, snus[28] [29] [30], is banned in the EU except for a derogation for Sweden. There is convincing evidence that the use of snus in Sweden can reduce the risk of people starting smoking [31] [32] [33]. There is also growing evidence that the use of snus in Sweden can help smokers to give up smoking[31] [33].

64. The only forms of smokeless tobacco allowed throughout the EU now are chewed products, often from south Asia, which tend to contain higher levels of carcinogens than the Swedish oral snuff products[34].

65. The need for regulatory standards in this area is therefore pressing. The EU is currently reviewing the scientific basis for the regulatory framework of smokeless tobacco. The UK Government has supported EU policy on smokeless tobacco, but the time has come for the UK to reassess its policy on this issue.

66. And, as a first step, it could look at setting toxin standards for smokeless tobacco products already on the market to match the standards for Swedish snus, known as the Gothiatek standard. There is emerging evidence that there is considerable variation among the chewing tobacco products available in the UK (with around 100 fold variation in levels of selected carcinogens and toxins)[34]. It is unacceptable that there are products currently on the market in the UK, and used

[25] McNeill A, Foulds J, Bates C. Regulation of Nicotine replacement therapies (NRT): a critique of current practice. Addiction 2001; 96:1757-68
[26] Protecting smokers, saving lives: The case for a tobacco and nicotine regulatory authority Prepared by the Tobacco Advisory Group of the Royal College of Physicians, December 2002
[27] Cogliano et al . Smokeless tobacco and tobacco-related nitrosamines. Lancet Oncology 2004; 5; 708
[28] Asplund, K. Smokeless Tobacco and cardiovascular disease. Prog. Cardiovasc. Dis. 2003 45:383-394.
[29] Levy, DT, Mumford EA, Cummings KM, Gilpin, EA, Giovino, G, Hyland, A, Sweanor, D, Warner, KE. The relative risks of a low-nitrosamine smokeless tobacco product compared with smoking cigarettes: Estimates of a panel of experts. Addictive Behaviour 2005.
[30] National Board of Health and Social Welfare. Folkshalsorapport 2005 (Public Health Report 2005).
[31] Furberg H, Bulik C, Lerman C, et al. Is Swedish snus associated with smoking initiation or smoking cessation? *Tob Control*.2005; 14:422-424.
[32] Rodu B, Nasic S, Cole P. Tobacco use among Swedish schoolchildren. *Tob Control* 2005; **14**:405-408.
[33] Ramstrom L, Foulds J. (in press). The role of snus in initiation and cessation of tobacco smoking in Sweden. Tobacco Control.
[34] McNeill A, Bedi R, Islam S, West R, Alkhatib, N, Haq F. Levels of toxins in oral tobacco in the UK. Tobacco Control. 2006;15:64-7.

predominantly by ethnic minorities, that are far less safe than the product, Swedish snus, that is banned by the EU.

67. If less harmful forms of smokeless tobacco such as those produced in Sweden were to be licensed it is our view that comprehensive pre and post introduction market surveillance would be crucial to ensure effective evaluation and monitoring. This would enable, for example, analysis of the impact on young people of the introduction of new products.

68. However, even if smokeless tobacco were to be regulated to a very high standard such as the Gothiatek standard used for Swedish snus, and promoted as a safer alternative to smoking, the advertising ban for all tobacco products should be maintained. Any marketing and advertising of smokeless tobacco that is allowed should only be within the context of smoking cessation, and aimed at existing smokers. It is crucial that it should not be allowed to be marketed to new customers, who are not already smoking.

Consumer understanding

69. Currently most smokers don't understand that it is the smoke and not the nicotine that does them harm. Unpublished data from smokers in October 2002 found that 57% of smokers believed that it was the nicotine that caused most of the cancer from smoking and similar numbers believe nicotine causes heart disease and asthma. A third of smokers thought that stop smoking products with nicotine are just as harmful as smoking As a result many do not even use the existing nicotine replacement products to help them give up smoking, and if they do, don't use them for sufficient time for them to be fully effective.

70. Currently only a very small proportion of those using NRT use it long-term, ranging from as little as 3% of nicotine patch users who pay for their medication still using after 15 weeks to 43% of those remaining tobacco-free for a year and receiving the nasal spray free still using it after one year. For most of those who give up using NRT it will be because they have relapsed and started smoking again, not because they have ceased using nicotine altogether.

71. Therefore the greater risk is not that cleaner nicotine products would be rapidly taken up by smokers and by new users but that such products might not be taken up by sufficient numbers and would not succeed in reducing smoking prevalence.

72. The addicted smoker would need to be encouraged to switch from tobacco to nicotine with a mixture of marketing and financial incentives. These new products need to be readily available and their role understood by consumers. This would require a mass communication campaign over a period of time, involving advertising, promotion and the involvement of health professionals, such as stop smoking advisers and GPs, in actively advocating switching from tobacco to cleaner nicotine sources. It is critical that this communication comes from trusted sources and not from the pharmaceutical industry.

73. The potential is vast. In Sweden, there has been a marked decline in cigarette smoking in men over the last 20 years, whereas the use of smokeless tobacco, in the form of snus, has increased significantly. Hence there was little change in overall tobacco use, but significant improvements in health.

74. Swedish men experienced a marked reduction in the incidence of the major smoking caused diseases. For example, in 2000 Sweden had a lower standardised rate of male lung cancer incidence than any comparable developed nation in the world and it also had a low rate of oral cancer which has been falling over the last 2 decades[35].

Reduced Ignition Propensity Cigarettes

75. A simple first step towards effective tobacco product regulation would be the setting of standards for Reduced Ignition Propensity (RIP) cigarettes. In 2003, 123 people died in the UK in smoking-related fires, there were a further 1,416 non-fatal injuries and 4,159 fires. The vast majority of fires causing fatalities and injuries are caused by manufactured cigarettes.

76. Such standards have already been introduced in New York in June 2004[36] [37]and Canada [38] and have now become law in numerous other US states. The Canadian Regulatory Impact Assessment forecasts a reduction in fires by between 34% (scenario 1) and 68% (scenario 2).[39]

77. This is corroborated by initial statistics from the Office of Fire Prevention and Control in New York State which show that 28 people died in 2004 from smoking-related fire deaths. That is down by one-third from the average of 42 smoking-related deaths in each of the three previous years for which reliable statistics are available.

78. A recent Fire Research Report by ODPM estimated that had cigarettes in the UK conformed to the highest standards on sale in New York in 2003, the number of smoking-related fires would have been reduced by nearly two thirds from 4,159 to 1,615, the number of fatalities from 123 to 45, and the number of non-fatal casualties from 1,416 to 530.[40]

79. Setting standards for RIP cigarettes is supported by the Department for Trade and Industry, the Department of Health and the Department for Communities and Local Government and would help the Government meet its health inequalities and social inclusion targets and PSA targets to reduce the number of accidental fire-related deaths in the home.[41] This could be achieved by setting technical standards under the General Product Safety Directive which is currently under investigation by the European Commission.

New regulatory framework

80. Nicotine is addictive; therefore, all nicotine products should be regulated. Competitive recreational nicotine delivery devices are only likely to be developed and licensed if there is a regulatory framework encompassing the range of nicotine delivery systems which encourages their development. This needs to

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[35] Foulds et al, The effect of smokeless tobacco (snus) on smoking and public health in Sweden. Tobacco Control.
[36] New York General Law. Ch 284. s.156-c. Cigarette Fire Safety Act, 2000. Available at: http://www.dos.state.ny.us/fire/amendedcigaretterule.htm . See also: http://www.dos.state.ny.us/fire/regulations.html#cigarette
[37] ASTM International is a U.S. based organisation that develops consensus testing methods. See: www.astm.org
[38] See http://www.hc-sc.gc.ca/hecs-sesc/tobacco/legislation/rip.html
[39] http://www.hc-sc.gc.ca/hl-vs/pubs/tobac-tabac/rias-reir/index_e.html
[40] http://www.odpm.gov.uk/index.asp?id=1163267
[41] http://www.hm-treasury.gov.uk/media//668C8/sr04_psa_ch5.pdf

require regulators to take into account the death and disease caused by cigarettes if smokers did not use the nicotine delivery devices.

81. For this to happen is likely to require a revised, if not a new, regulatory framework. The regulatory obstacles need to be removed, and replaced with policy levers that would encourage the development, promotion, pricing and retailing of less harmful nicotine products in direct competition with, and at a significant advantage to, cigarettes. It would also be necessary for health professionals to be involved in promoting understanding of the new products and their uses. Control of marketing and promotion would continue to be needed to ensure that non-smokers weren't encouraged to take up nicotine.

82. Other mechanisms could include tax advantages, new indications for pharmaceuticals, packing and consumer information, incentives for R&D, government funded research programmes to quantify the benefits or harm, consumer education and awareness, the setting of mandatory performance standards for toxic emissions and ingredients in tobacco products.

83. The HM Treasury could play a crucial role in setting tax differentials between the newly licensed products and cigarettes using price to trigger behaviour change, particularly amongst poorer users.

84. A new tobacco and nicotine regulatory framework which would enable such products to be developed and promoted would not have significant long term resource implications. The cost would be insignificant compared to the £7.8 billion raised from tobacco taxes each year and the £1.5 billion smoking is estimated to cost the NHS.

85. Ideally control of all nicotine products should be under one control agency. It is possible that there could be different regulators for tobacco and nicotine with nicotine remaining under the control of the MHRA but information would need to be shared between the regulatory bodies.

Next steps

86. A proper assessment is needed of how to regulate tobacco and nicotine. There are already existing models which give a good idea of the potential resources required. For example, the Canadian tobacco regulatory authority employs around 140 people at an annual cost of under £50 million, while the Irish Office of Tobacco Control employs only 13 people with a budget of under £2 million[42].

87. The cost of regulation should be charged to the tobacco industry, on the 'polluter pays' principle, for example through taxation or through a system of licensing. However, given the past behaviour of the tobacco industry[43] it would be critically important to prevent regulatory capture by the industry and therefore the regulators and the regulatory process would have to be completely independent.

88. One option might be to expand the remit of the Health Protection Agency which has responsibility for protecting people's health, and already has oversight of poisons and chemical substances and so has appropriate expertise. Another

[42] 2005 figures
[43] http://www.ash.org.uk/html/conduct/html/trustus.html

option could be for the MHRA to regulate smokeless tobacco as a smoking cessation product, as it already regulates medicinal nicotine.

89. Introducing regulation in either of these ways could be achievable in the short term. The remit should be to minimise the proportion of regular nicotine users in society, and amongst them, the proportion regularly obtaining nicotine through smoked tobacco.

90. The current regulatory regime in the EU means that we leave the most dangerous form of nicotine use – cigarette smoking – the least regulated, while certain forms of smokeless tobacco are illegal and medicinal nicotine, the least harmful form of use, is heavily regulated. It would make more sense to apply controls to nicotine and tobacco use in proportion to the amount of harm caused.

91. Nicotine and tobacco regulation should be:
    - independent from the tobacco and pharmaceutical industries;
    - minimise as far as possible delivery of toxins from smoked and smokeless tobacco products;
    - conducted with the aim of moving the market in nicotine towards reduced harm products;
    - ensure that marketing continues to be strictly controlled to discourage uptake of nicotine products by underage and new users;
    - with controls applied in proportion to the harm caused; and
    - set public health targets to reduce smoking prevalence and to help populations addicted to smokeless tobacco to quit.

92. With a harm reduction based regulatory framework one could expect to see new, less harmful but more attractive, products in development and being market-tested within 2-5 years.

93. Over the next 20 years, on a cautious extrapolation of current trends, tobacco and nicotine consumption will only decline to around 17% prevalence. If half of the total did not smoke but used alternative cleaner nicotine sources, it could save tens of thousands of lives and hundreds of millions of pounds each year.[3]

Conclusion

94. There is enormous potential to reduce health costs, narrow health inequalities and dramatically cut the numbers dying from smoking by substituting less harmful forms of nicotine for smoked tobacco. It would be a major lost opportunity if a policy on harm reduction was not developed by the Government as the next logical step in tobacco control.

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