

**Report on NICE Citizens Council meeting**

**Smoking and harm reduction**

**October 15-17, 2009**

## Contents

<b>What we were asked to do</b>	<b>1</b>
<b>What we concluded</b>	<b>2</b>
<b>How we worked</b>	<b>3</b>
<b>What we heard, and what we did</b>	<b>4</b>
Some basic facts	4
Initial scepticism	5
Speaking for and against harm reduction	7
First thoughts on NRT and on quitting	9
In support of harm reduction	10
An unusual combination: tobacco and pharmaceuticals	12
Meeting the smoker's needs	15
Communication problems	17
Feedback on communication	18
Feedback on smokers' perspectives	19
Voting and decisions	20
<b>Appendix 1: case studies</b>	<b>25</b>
<b>Appendix 2: voting on the importance of considerations</b>	<b>31</b>
<b>Appendix 3: tracker questionnaire results</b>	<b>33</b>

## **What we were asked to do**

NICE presented us with a series of aims and objectives for the meeting, and also requested us to answer two main questions and a list of subordinates.

The meeting's aims were as follows:

- 1) To explore the Council's views regarding the pros and cons of supporting smokers to quit and promoting the switch to 'safer' products such as medicinal nicotine.
- 2) To obtain a report that will be of use to NICE in developing its future strategy for developing guidance on tobacco control.

The objectives were:

- 1) To explore the Council's general views on promoting a smoke free society.
- 2) To explore what the Council's attitudes would be towards a policy that aimed to support smokers to quit while at the same time helping smokers switch to safer products.
- 3) To explore the Council's attitudes towards different approaches to harm reduction, in particular the difference between medical nicotine and other forms of tobacco products.
- 4) To explore the Council's attitudes about the possible safeguards around manufacture, marketing, distribution of such products.
- 5) To explore whether the Council think that there are any groups of people for whom the NHS should provide such products (e.g. COPD<sup>1</sup> patients).
- 6) To explore any differences in viewpoint dependent on what type of company the manufacturer is (i.e. whether a tobacco company or a pharmaceutical company).

The main questions we had to answer were:

- 1) Is 'harm reduction' a valid strategy?
- 2) What are the pros and cons of 'harm reduction' and encouraging quitting?

There were also eight subordinate questions to be tackled:

- 3) What are your views on promoting a smoke free society?
- 4) What would your attitude be towards a policy that aimed to support smokers to quit while at the same time helping smokers switch to safer products?

---

<sup>1</sup> Chronic Obstructive Pulmonary Disorder (COPD) is a progressive disease that makes it hard to breathe.

5) What are your attitudes towards different approaches to harm reduction, in particular the difference between medical nicotine and other forms of tobacco products?

6) What safeguards might you want to see in place around the manufacture, marketing, distribution of such products?

7) Are there any groups of people for whom the NHS should provide such products (e.g. COPD patients)?

8) Does it matter what type of company the manufacturer is (i.e. whether a tobacco company or a pharmaceutical company)?

### **What we concluded**

On the central, broad question of harm reduction as a valid strategy we voted 27 for and one against.

However, our discussions revealed that we held two overlapping views of its rationale and its goals. It could be seen as predominantly a means to an end (the end being for the smoker ultimately to quit); or more as an end in itself that would allow smokers to cut down and perhaps stop, but at the price of continuing to rely (perhaps indefinitely) on their chosen nicotine replacement. We therefore held two further votes, with the following results:

- A) Harm reduction as a way to quit smoking and break addiction. (26 of us voted in favour.)
- B) Harm reduction as a way to provide a less harmful alternative to smoking while accepting that nicotine addiction continues. (9 of us voted in favour.)

Because positions A and B are not wholly incompatible, a minority of us voted for both; hence voting figures.

We also compiled a list of the pros and cons of harm reduction strategies, and then voted on them. The complete list appears later in this report. Those pros and cons which garnered votes, and the numbers voting for them as most important in each of strategies A and B, are as follows:

#### Pros (definition A of harm reduction)

Less harm than cigarettes (NRT)	2
Reduces passive smoking	7
Prevents death	11
Reduces patient numbers with smoking related illnesses	8

#### Pros (definition B of harm reduction)

Less harm than cigarettes (NRT)	16
---------------------------------	----

Reduces passive smoking	2
Prevents death	2
Reduces patient numbers with smoking related illnesses	5
Opens path to a smoke-free society	1
Possibly more effective than the worn-out shock tactics currently used	1
Meets moral obligation to reduce harm	1

Cons (definition A of harm reduction)

Replaces one addiction with another addiction	11
There is still scope to improve the quitting approach, e.g. with more education and counselling	14
Clouds the ‘quit’ message	2
Individuals who want to quit should just quit	1

Cons (definition B of harm reduction)

Replaces one addiction with another addiction	14
There is still scope to improve the quitting approach, e.g. with more education and counselling	10
Clouds the ‘quit’ message	3
Risk of creating new addicts	1

We also compiled (and prioritised) a list of considerations that NICE should bear in mind if and when it is called upon to produce guidance on tobacco harm reduction strategies. This list and our priorities also appear later in the report.

We felt strongly that the tobacco industry should not become involved in harm reduction strategies. We also wish to emphasise the importance of disseminating more information on existing anti-smoking services, and making people aware of what they have to offer (many of us were unaware that these are free). It is also vital to correct widespread misconceptions about the ingredients in cigarettes that are most harmful, as opposed to what makes them addictive.

**How we worked**

Twenty eight of the members of our Council were able to attend the meeting, held from October 15-17 at the NICE headquarters in London. We began by completing the first of two tracker questionnaires. We spent the rest of the day listening to - and discussing - various medical, academic and commercial views on the significance of tobacco-induced ill health, and the role of harm reduction.

The second day included more presentations and a case study exercise in which, working in groups, we reviewed the three ways of delivering nicotine to would-be non-smokers to help them give up cigarettes. The day finished with the compilation of lists of the pros and cons of harm reduction strategies, and of the considerations that ought to be born in mind should NICE eventually recommend such a strategy. We also took a preliminary vote on the overall desirability of the harm-reduction approach.

On our final morning we completed a second tracker questionnaire, then devoted the rest of our time to discussing our ideas, reaching conclusions, and voting on what should go into the report.

We were able to question all the experts who spoke to us, and the meeting featured regular discussion in small groups, and collectively in our plenary sessions.

### **What we heard, and what we did**

#### *Some basic facts*

Professor Mike Kelly, director of the NICE's Centre for Public Health Excellence, began the day by explaining that while NICE had not yet been asked to offer advice on harm reduction, it might be. Our thoughts and conclusions would offer valuable help to a future guidance committee should Ministers request NICE to take a view on the issue. He then proceeded to remind us of the dismal facts about smoking and health, included the 87,000 smoking-related deaths in England alone, and their disproportionate concentration among lower socio-economic groups. Although the prevalence of smoking is on the decrease, it is clear that a substantial minority of smokers is still unwilling or unable to abandon the habit. Should we continue with the efforts already being made by Government and other bodies to persuade them to quit? Should we simply go on with the campaigns, the warnings, the offers of free help and advice and the rest of the approaches that have been used for many years to wean smokers off their habit? Or do we need - not necessarily instead of but perhaps in addition - to do something different? That something is "harm reduction": the provision of the addictive ingredient of tobacco in a form less damaging to health until the smoker felt able to live without it. The addictive component of tobacco, we learned, is nicotine. While it may not be entirely safe, nicotine is undoubtedly less harmful than the tar and the many toxic gases also found in tobacco smoke.

Following this brief introduction we were able to raise a number of issues with Mike Kelly. These included the general view that both sexes are

probably equally at risk of harm from tobacco smoke, that tobacco-related ill-health is greater in Scotland than elsewhere in the UK, and that illicit sales in the UK are currently thought to account for some 17 per cent of all tobacco products sold. One of us wondered why people in lower social groups were disproportionately affected. It seems there are many reasons, not least of which are lesser access to resources and to knowledge. But another factor is solace: the comfort of a cigarette when life is difficult. Under these circumstances, advice simply to “pull yourself together” is unlikely to be effective. Professor Kelly also assured us that data on the health effects of smoking are among the most reliable in public health.

At this point we broke into small groups to discuss what we had heard.

### *Initial scepticism*

In the feedback session that followed our small group discussions it became apparent that some of us were sceptical not just about harm reduction as an approach, but about the whole focus on tobacco. While a fall in tobacco smoking would undoubtedly be beneficial, is the problem posed by tobacco really more important than those of drugs or alcohol, we wondered. There are always people who will become addicted to *something*. And would it be sensible to replace one addiction with another: addiction to cigarettes with addiction to nicotine taken by mouth, for example? Would the availability of nicotine sources other than tobacco create new nicotine addicts who might never have used the drug because they would never have taken up smoking? And would the price of success in abandoning cigarettes be paid for with extra stress that might of itself be unhealthy? The cost to the NHS of doing more could be considerable – and fewer smokers would mean a loss of revenue to the government. As a society we don’t seem to be very good at coming to terms with death – though we all have to die sometime of something. But this was a very early stage of the meeting, and many of us were waiting for more evidence before beginning to formulate our ideas.

Mike Kelly commented that we had picked up on many of the trickiest problems! Responding to some of our comments he pointed out that death from smoking-related diseases is often exceptionally slow and painful, that stress is admittedly bad for you, that the association between tobacco and cancer was far stronger than that between alcohol and cancer, that addiction to ‘safe’ nicotine products was not associated with the same risks as tobacco addiction, and that a careful cost-effectiveness evaluation is among the tasks that NICE would need to carry out before it could make a recommendation. He also thought that a point made in one of the

our discussion groups – that perhaps it shouldn't be a harm-reduction strategy or a continuation of present programmes, but both in parallel – was important and would need to be explored. Personally, he said, he liked that idea.

He then took the microphone to give a second presentation, this time on the logic of the harm reduction approach. If the most toxic elements could be removed from tobacco smoke while giving smokers the nicotine “hit” they craved, fewer people would become ill. Unfortunately the cigarette is a most effective nicotine delivery vehicle. So what is needed is an alternative system that mimics the speed and strength of nicotine delivery by cigarette, but does not simultaneously deliver its most harmful constituents.

Harm reduction has been used in other areas of public health such as needle and syringe replacement schemes for intravenous drug addiction, and contraception to prevent unwanted teenage pregnancy. However, some critics see harm reduction as a cop out, claiming for example that it normalises deviant or illegal or harmful behaviour, condones immorality, and doesn't get to the root of the problem.

Professor Kelly sees harm reduction as presenting several challenges. First regulation; nicotine patches, sprays and gums are all highly regulated, so companies have no great incentive to organise expensive clinical trials to make products which, if they contained more nicotine, might not be licensed except for sale through pharmacies, and with restrictions on their marketing. Paradoxically, he added, the most dangerous form of nicotine delivery – the cigarette – is unregulated, widely available, and still heavily promoted!

Then there is the issue of communication. Many people still believe that nicotine is the most dangerous element in tobacco smoke. And there is also a possibility that smokers may be discouraged from trying to quit cigarettes if they learn there is safe alternative to smoking. Finally there is the possibility of unintended consequences. For example, nicotine may be more harmful than we think, because there is currently a lack of firm evidence on the safety of its long term use. And there is the possibility of inadvertently creating a new set of norms: a new form of addiction.

In our subsequent question and answer session we discussed the lengthy period that might be required to establish the safety of nicotine, particularly if any significant adverse effects turned out to be relatively rare; the cost of monitoring a highly regulated product; the dangers of

trying to get a bigger hit by consciously taking an overdose; and the possibility of creating a new type of drug user – the non-smoker who fancied a hit and got it through some form of nicotine replacement therapy (NRT).

*Speaking for and against harm reduction*

Our next speaker was John Britton of the UK Centre for Tobacco Control Studies at the University of Nottingham. He presented the arguments in favour of harm reduction by NRT. Besides the health benefits to be had from not smoking, these include an end to passive smoking, the disappearance of many adult smoking role models likely to encourage a new generation of young smokers, and even such indirect consequences such as fires caused by carelessly abandoned cigarettes.

As we had already heard, it is the practicalities of NRT that pose the major problem. Modified smoking products - allegedly safer forms of tobacco - had been tried and found wanting. This leaves medicinal nicotine and smokeless tobacco.

The former have local effects at the point of administration - through the skin, in the mouth etc - but these are generally mild and transient. Claims have been made about more severe effects including heart attacks, stroke, birth defects and cancer. But in some cases, according to John Britton, the evidence is weak; in others the effects may be real but also rare by comparison with the effects of cigarette smoke.

He too talked of the relative lack of a hit with administration by this route – and illustrated the substantial differences with a series of measurements of blood nicotine levels. Higher dose levels are available in some of the products sold or dispensed at pharmacies – but even the highest currently available does not compare with cigarette delivery. He also presented international data on the widespread belief that nicotine causes cancer. The belief is most common among those on low incomes. The figures also show that a quarter to a third of people believe that NRT too might harm health.

In the meantime, medicinal nicotine would be more viable if it were delivered at a higher dose, given an unequivocal health endorsement, priced more cheaply than cigarettes, sold over the counter and marketed more attractively.

Smokeless tobacco includes products designed to be chewed or sucked. The best known is the Swedish snus, a form of reconstituted tobacco that

comes in small “tea bag” placed between the upper lip and the gum. This has no known link with bronchial disease, and no major effect on heart disease. The sale of snus is illegal everywhere in the EU except Sweden – where its use has overtaken that of cigarettes. Sweden has one of the lowest smoking rates in Europe: a position partly though not wholly attributable to snus use.

Gunilla Bolinder of the Karolinska University Hospital in Stockholm takes a very different view. She believes that the only true harm reduction is to prevent smoking altogether, and argues that there is still mileage in existing methods of encouraging smokers to quit. Her presentation focussed on snus in particular, and she listed its disadvantages. It can cause cancer, she said, making it clear that she does not share John Britton’s relatively benign view of its side effects. It increases the risk of diabetes and can damage foetuses – though she did agree that all these actions are on a lower scale than would be seen with smoked tobacco.

She went on to point out that the Greek physician Hippocrates had famously said “First do *no* harm”, not “Do *less* harm”. Is it right for doctors to promote any alternative tobacco product, even if such a product is less harmful than smoking? Her answer was an unequivocal no. Moreover, she does not grant snus much of the credit for the fall in smoking that has taken place in Sweden, from 45 per cent in 1969 to 14 per cent in 2007. The arrival of snus, she claims, has simply created a new category of drug user. It is marketed to young people, is often more addictive than smoking, and is not sold with the aim of encouraging users to give up smoking.

Although not enthusiastic about other forms of NRT, she does accept that some of these do have a place in the anti-smoking tool kit. They are intended as a medical therapy for a limited time, they have less addictive potential than smoking, and they are not marketed to create new addicts. Snus, she insisted, is not so much needed for smoking cessation as for saving the life of the tobacco industry.

We discussed the two presentations with their authors, beginning with the issue of anti-tobacco campaigning, and the question of whether we are sufficiently imaginative in targeting particular messages at particular groups, especially the young. Both speakers agreed on the importance of pushing the right buttons if you were going to reach your chosen group. The questioning then moved to the labelling of cigarette packets and the case for listing all the toxic ingredients. We also learned that snus use is socially acceptable in Sweden in the way that smoking used to be. John

Britton took this opportunity to emphasise that while snus had proved acceptable in Sweden, it wouldn't necessarily be a right or desirable solution for Britain. He had been quoting it solely to demonstrate the feasibility of a widespread use of some form of NRT.

One of our members raised the problem that many young people feel "invincible"; they find it difficult to take seriously the idea of ill health let alone death. Neither speaker could offer any instant guidance, but John Britton pointed out that the likelihood of any young person becoming a smoker is determined in part by the prevalence of the habit among the adults they mix with. In the UK, the prevalence of smoking among the very young is now falling quite rapidly.

Before answering a question on the marketing of NRT, John Britton emphasised that he agreed with Gunilla Bolinder that cessation was the ideal way to deal with smoking. The problem lay with the hard core who proved resistant to giving up. If we are to make a success of NRT, it had to be cheap, attractive and easily available. But while liberalisation of the nicotine market is important, it has to be carefully thought-out and regulated. Over-regulation leads to high cost and little competition.

Would young people simply become addicted to some form of NRT instead of cigarettes? John Britton didn't see much likelihood of children going behind the bike sheds to share a non-smoking nicotine product. Other topics discussed were the source of medicinal nicotine (also from tobacco), and the extent to which at least part of the attraction of snus is the business of putting something in the mouth (like a baby's pacifier).

#### *First thoughts on NRT and on quitting*

At this point we once more divided into small groups to discuss what we had heard so far, and then report back. The first group to do so had compiled a list of the pros and cons of NRT. On the positive side, they said, was that it might help people who want to give up but can't. Their list of cons was rather longer and began with the view that simply to quit smoking was the preferred option, even if it did rely on willpower. They were also worried about the side effects of NRT, that it might even tempt some ex-smokers to return to smoking, its cost-effectiveness, and the assumptions that what might be a long process would have to be paid for by the NHS.

The second group felt there were currently insufficient incentives to encourage people to stop smoking. And who is being targeted; is it smokers, or people who don't yet smoke? Noting that there were already

several alternative methods of NRT available to smokers, they wondered what evidence exists of their relative effectiveness. They also wondered what effect the smoking ban has had; it would be useful to know. (We were later told by NICE of some evidence that more people are trying to give up. In Ireland the number of people trying to quit had initially risen, but then dropped back.)

The final group concurred with much that had already been said. They added that some of them had felt that if only 10-15 per cent had problems giving up, why not simply carry on with the existing smoking cessation programme? They were struck by the suggestion that new products will create new addicts. They were also concerned by the cost of alternatives, the control of advertising, and whether nicotine really is as innocuous as is believed. They warned of the need to look out for hidden agendas among the proponents of the different approaches to smoking.

#### *In support of harm reduction*

Following the lunch break we heard from the first of two people broadly sympathetic to the need for a programme of harm reduction. The first, Nicky Willis - chief executive of the newly created NHS Centre for Smoking Cessation and Training - explained that her organisation was currently in process of putting together an anti-smoking strategy that places special emphasis on high prevalence communities and high risk groups. She and her colleagues are considering what might be included in a harm reduction strand among the activities under consideration.

She outlined the current work of the NHS Stop Smoking Service, and the extent to which it can help people who wish to quit. It does offer NRT to people who use it, but only as an aid to abrupt quitting. It does not provide NRT on a longer term basis. As she said, smokers who are trying to cut down on or give up cigarettes without outside help are already using NRT for temporary abstinence; more rarely they also NRT in the long term, following cessation.

The possible approaches she outlined are: temporary substitution with medicinal nicotine; partial substitution for those not willing to set a quit date; high dose treatment for high dependence smokers; and long term use. For NHS Stop Smoking Services to use these approaches would require further research to check their efficacy, the development of new treatment protocols and perhaps delivery methods, staff retraining, access to extra funds, and publicity designed to persuade the public of their value and fitness for purpose. The evidence suggests that even if NRT was used as a long term substitute for cigarettes, harm would be greatly

reduced. There is also evidence that partial substitution of NRT for smoking helps some people go on to quit, although it may divert others.

Overall, she concluded, there is currently a lack of provision for smokers who wish to do something about their smoking but are not yet ready to quit, and NRT could help them in what would appear to be a cost effective manner.

The next speaker, Deborah Arnott of the Pressure group ASH (Action on smoking and Health) was adamant about the potential benefits of NRT. She argued that existing strategies are simply not enough and, that while quitting is still the best option, partial or complete substitution with nicotine offers a less harmful alternative to smoking – provided it is kept out of the hands of the tobacco industry. Like previous speakers, she drew attention to the people who faced the greatest difficulty: the poor and underprivileged. She also emphasised the benefits of NRT to non-smokers and to the vulnerable including pregnant women, people with lung disease and angina or who've had a heart attack or a stroke. None of them would be at risk of passive smoking.

She also considered arguments against harm reduction strategies such as the encouragement of addiction and the possibility of it acting as a gateway into smoking for younger people. As far as the former was concerned she viewed NRT as less addictive than smoking, and a halfway house to cessation; commenting on the latter she felt that the real gateway into smoking was to grow up in a smoking household. She added that NRTs were not actually very attractive.

An effective policy would need to be promoted, with the less harmful alternatives to cigarettes at least as freely available, perhaps in the same points of sale. They should be able to compete on price – which will become easier if the cost of tobacco continues to rise. There should be increased competition in the medicinal nicotine market to foster price cuts. The Department of Health should lead on any strategy, with some NRTs sold over the counter and others on prescription. There would need to be guidance from NICE on the length of time for which it would be safe and acceptable to continue using NRTs. The long term goals might include: a lessening in smoking-related health inequalities; the reduction of tobacco use to less than five per cent of the population; and a steadily falling rate of smoking-related morbidity and mortality. All in all, she concluded, this strategy would be one of the most important public health measures imaginable.

We discussed some of the issues arising from the presentations. One of us referred to the restrictions on certain people seeking NHS operations who continue to smoke after a warning by the surgeon that to continue doing so would prejudiced the outcome of the procedure. In response to the question, the speakers said they would be reluctant to see denial of surgery used as a threat applied not for medical reasons but solely to force smokers to quit. However, episodes of hospital care for whatever reason are still an underexploited opportunity to remind patients of the hazards of smoking, and to offer practical help and advice.

Another Council member reminded the speakers of smokers' need to get a nicotine hit, and wondered about the likelihood of NRT giving it to them. The point was well taken, and it was agreed that there is a need for products that supply sufficient nicotine. Manufacturers need encouragement – and a policy framework within which to do it. Deborah Arnott added that she believed the manufacturers could bring the price down now if they so wished to. But in the absence of serious competition there is little incentive.

On the question of dose there is a case for using a combination of therapies: a patch, say, to give a steady background dose of nicotine supplemented by a spray or gum as required. One of our members commented that this is surely an area in which more information needs to be supplied to the public. The point was well-taken.

Another of us suggested that self-help groups who can apply peer understanding and pressure in particular communities had a role to play. The speakers agreed.

#### *An unusual combination: tobacco and pharmaceuticals...*

The next two presentations offered us the unusual sight of representatives of the tobacco and pharmaceutical industries sitting side by side on the same panel. Speaking for the former, David O'Reilly of British American Tobacco began by quoting WHO data on smoking-related deaths (the industry no longer holding to its former view that smoking is a harmless activity) and the likely future of tobacco smoking. As far as harm reduction is concerned, he said, his industry's aim was to reduce harm by evolving a portfolio of commercially successful lower risk products. He added that this can only succeed if his industry's efforts are supported by others, and at present the public health policy environment is not supportive. He quoted, with approval, the way in which the consumption of cigarettes in Sweden had fallen in parallel with an increase in the use of snus. The Swedes, he said, had the lowest consumption of cigarettes in

Europe, and highest of smokeless tobacco. This finds a reflection in their low rates of cancer mortality and other forms of smoking-related death. Snus is a gateway out of smoking, and (among people who start on snus) a barrier to their taking up smoking. He himself had switched to snus (for our benefit he subsequently demonstrated how snus is used) and reported that it had taken him a while to get used to it. The industry is building up a capability for making new products, and test marketing some of them. But there will be no great movement unless and until the policy environment becomes more supportive.

The representative of the pharmaceutical industry was Ben Carrick of Johnson & Johnson, makers of Nicorette gum, patches, inhalators and nasal sprays. The company has been involved in NRT for 30 years: an involvement that began when, with the University of Lund, the company had been asked to find a remedy for the withdrawal symptoms of submariners unable to smoke while underwater. It was claimed that the products are both effective and cost-effective. They are used for smokers who have undergone abrupt cessation, or are following a programme of cutting down. He said he was in favour of the development of a harm reduction strategy for both these purposes, but especially with the aim of achieving the complete abandonment of smoking.

He believed there is now strong support in the UK for harm reduction. But he also felt that a number of conditions would have to be met before such a policy became fully viable.

- Quitting tobacco should be the first option. Harm reduction should be a secondary strategy for those who cannot manage that.
- The alternatives to tobacco should be medicinal nicotine products of demonstrable safety.
- The products should be widely and easily available.
- Medicinal nicotine should be available to smokers for longer term use than is currently permitted. Where the alternative is a return to smoking there should be no upper time limit imposed. Tobacco dependence is a chronic and relapsing disorder
- There should be public endorsement by government and by public health specialities. There is already confusion and uncertainty that needs to be overcome.
- All products should be regulated within a medicinal framework. Without this an already confused situation will become even more so.

At this point the speakers were joined by two colleagues (Alan Porter of Imperial Tobacco, and Johnson & Johnson medical director James

Walmsley) for a question and answer session. In response to our first enquiry the panellists, and particular the pair from the drug industry, made it clear it that while both have specialist knowledge that is relevant to NRT, the likelihood of the two industries joining together in any kind of collaboration is slim. The tobacco industry might not be averse, but its pharmaceutical counterpart would face something of a public relations problem.

One of us wondered whether any effort had gone into the issue of pricing and packaging NRTs. It has, according to the Johnson & Johnson representatives who talked of experiments with smaller packs (it had been a struggle to sell them, and they were eventually discontinued), and of pricing strategy. At the selling price to the Government of prescription NRTs they had been shown to be highly cost-effective. Over-the-counter products ranged from £15 per week for patches to £21 per week for the nasal spray. This is less than most smokers spend on cigarettes.

Other topics discussed were the source of the nicotine used by the drug industry (fine chemicals companies), the revenue derived by the Government from sales of tobacco (vast), why people start smoking in the first place (many reasons including, among the young, curiosity), the effects of the ban on smoking (some reduction in use, but price is the really big factor), and the illicit tobacco trade (the industry actively co-operates in trying to eliminate it).

Following a final 30 minutes of small group discussion we reconvened to report back to the whole group. The first group to speak admitted to a feeling of confusion; while many of the experts seemed to favour a harm reduction approach, it was less clear precisely which route should be followed. The group itself was split over the desirability of introducing a snus-like product. They were also left with a number of questions: who should pay for the substitutes; how long they should be used for; and whether harm-reduction would reduce costs to the NHS overall.

The second group found itself in sympathy with harm reduction for its relative invisibility and so its reduced likelihood of encouraging others to take up the habit. But it felt that harm reduction should be run in parallel with cessation programmes, and not introduced without careful research to look for hidden snags. As far as promotion is concerned, this should emphasise NRT as a route to cessation. Price should be competitive with cigarettes, products should be more readily available, and more education about nicotine needs to be offered.

The third group felt that anything likely to reduce NHS costs is worth a try, subject to the findings of longer term trials. They didn't greatly mind who produces NRT products, so long as there is proper regulation. They disagreed on whether products should be available over the counter. They also drew attention to the need for education about nicotine and the other products in cigarettes smoke.

Professor Kelly finished the session and the day by reflecting on what he had heard of our discussions including those on price, the need to know who would use NRT products and how, where and with what restrictions and monitoring they might be sold, and by whom they might be made. All issues that NICE itself would have to ponder once it had seen our report.

### *Meeting the smoker's needs*

Our second day began with another presentation, this time from Professor Martin Jarvis of the Health Behaviour Research Centre at University College, London. He started by encapsulating the problem with a 1972 quote from a tobacco industry executive: "The cigarette should be conceived not as a product but as a package. The product is nicotine. Think of the cigarette pack as a storage container for a day's supply of nicotine...Think of the cigarette as the dispenser for a dose unit of nicotine...Smoke is beyond question the most optimised vehicle of nicotine and the cigarette the most optimised dispenser of smoke." Small wonder that the problem of smoking is a tough nut to crack.

Martin Jarvis reminded us of the importance to many smokers of the peak dose of nicotine: the hit. Snus will give a moderately high blood level – but not immediately. That said, it is clearly effective enough to have brought radical change to the use of tobacco in Sweden. Its importance to the rest of us is proof of principle: non-combustible forms of tobacco can be acceptable and even, at a population level, win out over cigarettes. Unfortunately, sprays, gums, inhalers and patches come nowhere near delivering a dose sufficient to create a hit. Users normally get no more than 40 per cent of the cigarette smoker's nicotine level. But they do appear to be safe, and reduce the intensity of withdrawal symptoms; their use doubles the chances of successful quitting.

The electronic cigarette or "e-cigarette" is a battery-powered device that provides inhaled doses of nicotine by heating a solution of it into a vapour. But for all their growing popularity there is so far little solid research evidence to back the claims made for these devices. The delivery of nicotine to the blood does not compare favourable with that of a

nicotine inhaler. Nor is there much compelling evidence to back several other novel devices Professor Jarvis told us about. What we can do, he concluded, is list the specifications for a new generation NRT product. It should have the capacity to raise the blood level of nicotine quickly (that is, by at least 10 nanograms per millilitre in ten minutes), it should have a formulation that avoids local side effects, it should incorporate sensory properties and behavioural rituals of the kind that help to make cigarette smoking so attractive, and it should allow users to regulate their nicotine blood concentration.

Our next task was to be an assessment of three NRT methods – but before that we had a chance to discuss Professor Jarvis’s views with him. The first issue raised was whether cigarettes are more or less hazardous than they used to be. Manufacturing methods have changed greatly, we learned. But there is no good evidence to suggest that they are now more toxic; indeed, they are possibly less so. The smoke itself may be more pleasant, but there is little reason to believe it is more addictive. Further questioning brought a reminder that the pharmaceutical companies had behaved quite conservatively in setting the dose limits on the nicotine content of NRT. The delivery of a higher dose is one way forward, and Professor Jarvis told us that he wouldn’t be surprised to see a product of this kind in the relatively near future. Another of us wondered if snus would deter people who might otherwise have taken up smoking from ever doing so. Professor Jarvis thought this was possibly so. Other topics we raised included alternative chemicals to nicotine (amphetamine was once considered a potentially useful way to get people off cigarettes, but didn’t live up to expectations), why snus delivers nicotine more rapidly than gum (partly a consequence of the alkaline environment it creates within the mouth), and its legality.

At this point we again split into three groups, each of which was asked to spend 45 minutes studying the details of one suggested NRT (see Appendix One) and then to report back. The first group to do so had been considering a product we’d already discussed at length, snus. They concluded that it would, as claimed, save lives and was vastly less toxic than cigarette smoke. Its use also eliminates passive smoking. But it does have adverse effects including a risk of cancer, it is itself addictive, and it doesn’t directly eliminate the original problem. The group was uncertain how much it might cost. Of the 11 in the group, four favoured its use, six were opposed, and one was undecided. They concluded that because it delivered a hit it would contribute to harm reduction (though this was not a goal shared by everyone in the group).

The second group to report had been looking at nicotine gum. As a harm reduction product it is easy to use, safe, creates no problems with passive smoking, and is unlikely to be taken up by non-smokers. But it is still addictive, can cause minor side effects, and is relatively costly. Would it work? Yes, for some people, because we already know this from experience – so long as those concerned have made a decision for themselves that they want to cut down or stop smoking. The current product looks “medicinal”, and isn’t particularly attractive as a consumer item. That could be seen as good or bad.

The last group had reviewed a device for delivering an aerosol of nicotine to the lungs, a kind of inhaler. On the plus side it appears to get nicotine into the bloodstream as rapidly as a cigarette, though at a rather lower dosage. It would be unlikely to be taken up by non-smokers. On the minus side it is clearly a medical rather than consumer product, and there are still questions to be answered about cost and safety. Maybe it should be tried only after other methods such as nicotine gum have been seen to fail, or alternatively kept for the hard core of smokers.

### Communication problems

Harm reduction presents two great challenges, according to the speaker in our next presentation. These are getting people to quit, and preventing the tobacco industry from exploiting any “muddiness” in the anti-tobacco messages required to achieve this. Professor Gerard Hastings of the Institute for Social Marketing and the Centre for Tobacco Control Research began by arguing that if 22 per cent of the UK population still smoked while the comparable figure for California was only 13 per cent, there was still mileage in persuading people not just to cut down but to quit. He claimed that the very existence of harm reduction strategies risks reinforcing the widely held perception that giving up completely is hard to do. Therefore, he said, getting people to quit smoking must remain the priority - even if this is not achieved on the first attempt. People who fail, not just once but perhaps on many occasions, should be encouraged to persevere.

The history of the tobacco industry, he went on, demonstrates that while they no longer deny that smoking is harmful, they still oppose any measure that might lead to further reductions in its use. They have a vested interest in doubt, and in watering down the key public health message: don’t use tobacco. They are also eager to enhance their public image – in which context Professor Hastings expressed the view that NICE had been “naïve” in inviting them to our meeting. It would, he predicted, be used as PR, especially in developing countries.

Harm reduction, he concluded, was appropriate only in the context of a properly regulated nicotine market. Without this it risks not reducing but actually increasing harm.

Our first question to Professor Hastings concerned what he see as the size of the UK's hard core of smokers who might need the help of a harm reduction strategy. He said he couldn't put a figure on it, but it was clear we yet to reach it. Nor indeed did he think that even the Californians had reached it.

One member of the Council reminded us that people of an earlier generation of smokers had had no option but to quit by themselves; there were no other resources available to help them. Another member commented that he disagreed with Professors Hastings about the NICE invitation to the tobacco industry to attend the meeting. He felt that it was important to hear from them direct.

We also discussed the greater difficulties of giving up if you are poor and disadvantaged. Social norms in this group have not yet shifted as far or as fast away from smoking as those of people in higher socioeconomic groups. But when they do succeed in giving up, it registers as something to be proud of.

#### Feedback on communication

We then went back into small groups to discuss what we had heard about communicating the harm reduction message, and how NICE should approach the task, should it need to do so. Each group returned with a list of items, many of them overlapping.

- NICE should emphasise the importance of knowing who is being targeted
- Messages should aim to help smokers quit, and encourage them by highlighting their achievements, even if they don't succeed first time. Failure can be part of the process
- The wording of messages must be carefully chosen, where necessary in a brutal but truthful way
- It is important for harm deduction strategies to avoid any clouding of the message that quitting is still the best option
- Communication at an early age is important. It would be better to deter people from starting to smoke rather than trying to stop them when they have already started
- Peer influence should be encouraged

- NICE should study what seems to be working at the moment

One of the groups wanted to emphasise that if harm reduction does emerge as a strategy to be followed it will need to be regulated. Members added that it will take a lot of resources - for which reason it might be best to start with groups than with individuals.

Our last formal presentation was given by Dr Jenny Fidler of the Health Behaviour Research Centre at University College, London. Her theme was smokers' behaviour and attitudes to harm reduction, and her findings were based on the results of monthly household surveys carried out on 1700 adults in England. These revealed that 56 per cent of smokers were trying to cut down, and 25 per cent of them were using NRT. This was most common among smokers aged 35 or over, and those who'd already tried unsuccessfully to quit. The findings also showed that cutting down does seem to encourage people to go on to quit. She couldn't find evidence that using NRT boosted this progression, but added that the sample size might still be too small to show it.

#### *Feedback on smokers' perspectives*

Following small group discussions we reconvened to report back on our conclusions about smokers' perspectives. The first group wondered who exactly the hard core smokers were, and what percentage of the population they constituted. Were their numbers sufficient to be worth spending a great deal of money on? And by offering NRT would we simply be sustaining their addiction? And who would pay? The long term hope - the only hope for some people - might be that smoking becomes totally socially unacceptable. Using NRT might also pose challenges in everyday use; would people feel comfortable using them among friends? Would-be non-smokers can't always count on support.

The second group to report back felt that more education about smoking in general was important if a younger generation was ever going to stop. The expansion of existing anti-smoking support groups would surely be helpful. In the first instance, at least, resources should be targeted at those who have already expressed a desire to give up. If people really want to continue smoking, it remains their right to do so. The third group particularly endorsed the need for more education.

In general discussion one of us added a further thought about the question of who would pay for NRT. We don't give smokers cigarettes for life, he

pointed out; why should be they be given NRT gum (or whatever) for life?

In a further briefing on basic facts about smoking from NICE we learned that harm reduction has been a topic of discussion in public health circles for some years. It is for this reason that NICE feels the need to get ahead of the game, even though it hasn't yet been asked to offer guidance.

We next split again into small groups to begin discussing what we would like to see in our report. We began with a preliminary vote on our broad view of the desirability of harm reduction strategies. Two groups voted by a substantial majority in favour, the third by an equal majority against. Overall 16 of us at this stage were in favour, 11 were against, and there was one "don't know". Each group then offered its list of the pros and cons of harm reduction. In the case of pros, we also added a further list of conditions that we felt ought to be attached to the use of NRTs. Overnight our facilitators collated these into a single list.

### *Voting and decisions*

We began our final day by agreeing on a couple of key messages we thought it important to communicate to NICE. First, that there is a need to disseminate more information on existing anti-smoking services, and make more people aware of what they have to offer. Second, that it is also important to correct widespread misconceptions about the ingredients in cigarettes that are most harmful, as opposed to what makes them so addictive.

We next offered our own personal definitions of what constitutes a harm-reduction strategy. Although we were still interpreting the term in many different ways, our views fell into one or other of two broad perspectives. Some of us saw harm reduction simply as an alternative for smokers who couldn't give up; other felt that while anything was better than smoking, quitting had to remain the ultimate goal.

At this point we carried out the first of our formal votes. On the basic question of whether harm reduction is a valid strategy we voted 27 for and one against. But because motivation (a means to an end, or an end in itself) had emerged as a factor in our discussion of harm reduction strategies, we also voted on two overlapping views of its rationale and its goals:

- A) Harm reduction as a way to quit smoking and break addiction. (26 voted in favour.)

- B) Harm reduction as a way to provide a less harmful alternative to smoking while accepting that nicotine addiction continues. (9 voted in favour.)

The first proposition can be described as an enhancement of existing policy that moves on from where we are now; the second is a more radical alternative. (The numbers voting add up to more than the number of Council members present because we felt that the two propositions were not mutually exclusive. Either way a majority favoured harm reduction, albeit for differing reasons.)

On the undesirability of snus as an alternative to smoking there was near unanimity. Likewise we felt strongly that the tobacco industry should not become involved in harm reduction strategies.

At this point we moved on to prioritise the list of pros and cons of harm reduction strategies that we had suggested the previous afternoon. Each of us chose our top pro and top con. Because we now had two core definitions of harm reduction (A and B), we produced lists for both of them. The figures below indicate the number of us who identified each issue as most important. Topics in **bold** are those which at least one of us rated as most important.

Pros (definition A of harm reduction)

1.	<b>Less harm than cigarettes (NRT)</b>	2
2.	<b>Reduces passive smoking</b>	7
3.	<b>Prevents death</b>	11
4.	<b>Reduces patient numbers with smoking related illnesses</b>	8
5.	Incentivises new NRT product development	
6.	Opens path to a smoke-free society	
7.	Possibly more effective than the worn-out shock tactics currently used	
8.	Helps people gain will to quit	
9.	Saves lives of 'hard core' who can't quit	
10.	A long-term investment in health	
11.	Meets moral obligation to reduce harm	

Pros (definition B of harm reduction)

1.	<b>Less harm than cigarettes (NRT)</b>	16
2.	<b>Reduces passive smoking</b>	2
3.	<b>Prevents death</b>	2
4.	<b>Reduces patient numbers with smoking related illnesses</b>	5
5.	Incentivises new NRT product development	

- |     |   |   |
|-----|---|---|
| 6.  | <b>Opens path to a smoke-free society</b>                                     | 1 |
| 7.  | <b>Possibly more effective than the worn-out shock tactics currently used</b> | 1 |
| 8.  | Helps people gain will to quit  |   |
| 9.  | Saves lives of 'hard core' who can't quit                                     |   |
| 10. | A long-term investment in health  |   |
| 11. | <b>Meets moral obligation to reduce harm</b>                                  | 1 |

Cons (definition A of harm reduction)

- |     |  |    |
|-----|--|----|
| 1.  | Cost to taxpayer   |    |
| 2.  | Not the best use of finite resources   |    |
| 3.  | Queries about safety of long-term NRT use  |    |
| 4.  | Addiction is not acceptable  |    |
| 5.  | <b>Replaces one addiction with another addiction</b>   | 11 |
| 6.  | <b>There is still scope to improve the quitting approach, e.g. with more education and counselling</b> | 14 |
| 7.  | Need to reduce rather than sustain addiction   |    |
| 8.  | <b>Clouds 'quit' message</b>   | 2  |
| 9.  | Risk of creating new addicts   |    |
| 10. | NRT delivery systems still experimental  |    |
| 11. | <b>Individuals who want to quit should just quit</b>   | 1  |

Cons (definition B of harm reduction)

- |     |  |    |
|-----|--|----|
| 1.  | Cost to taxpayer   |    |
| 2.  | Not the best use of finite resources   |    |
| 3.  | Queries about safety of long-term NRT use  |    |
| 4.  | Addiction is not acceptable  |    |
| 5.  | <b>Replaces one addiction with another addiction</b>   | 14 |
| 6.  | <b>There is still scope to improve the quitting approach, e.g. with more education and counselling</b> | 10 |
| 7.  | Need to reduce rather than sustain addiction   |    |
| 8.  | <b>Clouds 'quit' message</b>   | 3  |
| 9.  | <b>Risk of creating new addicts</b>  | 1  |
| 10. | NRT delivery systems still experimental  |    |
| 11. | Individuals who want to quit should just quit  |    |

With this vote complete, we moved on to the considerations and/or conditions that NICE should bear in mind when it is considering whether or not to advocate a harm reduction strategy. The list of considerations was based on the combined output of views expressed during our small group discussions of the previous afternoon. Each of us now chose our

top five – again for both the A and B versions of a harm reduction strategy. The complete list of considerations was as follows:

1. The need to focus on getting people to quit/not start smoking
2. The need for education about nicotine's effect on health (relatively harmless)
3. The difference between tobacco-based harm reduction products, e.g. snus, and pure nicotine harm reduction products, e.g. patches, gum, inhalers, etc.
4. The need for age restriction
5. The need for medical and behavioural support
6. Availability (i.e. where would harm reduction products be sold?)
7. The need for prescriptions for higher dose products
8. Value for money
9. The need for harm reduction products not to be attractive to young non-smokers
10. Quitting should be the primary message
11. Affordability
12. Price relative to price of cigarettes
13. The need for regulation
14. The need for products to be tailored to the end-user
15. Shared funding from NHS and pharmaceutical companies
16. The need for research into the long-term effects of NRT
17. The need for education that it is not the nicotine that kills but the other toxins in tobacco smoke

The pattern of our voting – we listed first, second, third etc choices for both our A and B definitions of harm reduction – appears in Appendix Two.

### Tracker questionnaires

For the responses to all the questions, see Appendix Three. Many of the results speak for themselves, but a few merit comment. Question 2 reveals that we had rather less sympathy for smoking at the end of the meeting than at the beginning, and question 4 suggests that the event had been educative, at least far as government policy on smoking is concerned. With regard to the issue of whether the only way to reduce the harm done by smoking is to encourage people to quit, the responses to question 5a suggest that while the spectrum of our opinion had widened somewhat, more of us felt by the end of the meeting that quitting is the best way of achieving this end. There was less shift of opinion on 5b, the question of whether or not harm reduction is a valid strategy for those who cannot quit.



## Appendix One: Case study details

### Citizens Council on Smoking and Harm Reduction

#### Case study on Medicinal Nicotine (Nicorette® 4 mg gum)

It has been suggested that medicinal nicotine, or nicotine as a medicine (as opposed to nicotine in a cigarette) should be used as part of a harm reduction approach to tackling the problems of smoking. An example of this thinking is the following summary of a chapter in ASH's report 'Beyond Smoking Kills' (p.58):

#### ***Smokers who are currently unable or unwilling to quit***

*Smokers are harmed by the tar and toxins in tobacco smoke and not by the addictive chemical which keeps them hooked: nicotine. Unfortunately there is no way of avoiding these toxins if you inhale the smoke from burning tobacco; there is no such thing as a toxin-free cigarette. There are, however, other ways of consuming nicotine without having to light up.*

*It is possible for smokers to satisfy their nicotine dependence without being exposed to the risks of tobacco smoke by switching from tobacco to pure nicotine products. These are products which, like the current medicinal products on the market, contain only nicotine and not other tobacco derivatives.*

*Currently pure nicotine products are not marketed or priced in a manner that makes them attractive as direct alternatives to smoking, rather than as aids to quitting. As a result, smokers who are currently unable or unwilling to quit are denied the choice of maintaining their nicotine dependency at greatly reduced personal risk.*

One of the most commonly used forms of medicinal nicotine is Nicorette® 4 mg gum. Packets of this product contain little squares of chewing gum (each containing 4 mg of nicotine, as nicotine resinates) which users are directed to chew when they have a craving to smoke.

Nicorette® is a licensed medicine in the UK. However, it is not currently licensed for use as a part of a harm approach approach, i.e. as a permanent substitute for cigarettes. The Summary of Product Characteristics for

Nicorette® 4 mg gum explains what it is licensed for (its 'therapeutic indications') as follows:

*Nicorette 4mg Gum is indicated for the relief of nicotine withdrawal symptoms as an aid to smoking cessation in adults and children over 12 years of age. It is also indicated in pregnant and lactating women (see section 4.6).*

*In smokers currently unable or not ready to stop smoking abruptly, the gum may also be used as part of a programme to reduce smoking prior to stopping completely.*

*If possible, Nicorette 4mg Gum should be used in conjunction with a behavioural support programme.*

The full Summary of Product Characteristics for Nicorette® 4 mg gum is available to you separately, as is the Patient Information Leaflet, which is put into every packet. As well as explaining what Nicorette® 4 mg gum should be used for and how it is to be used (i.e. how to chew it), these documents also explain Nicorette® 4 mg gum's contraindications (the situations in which it should not be used) and its possible side-effects, from the common (e.g. sore mouth) through the rare (e.g. allergic reactions) to the very rare (e.g. abnormal beating of the heart)

## **Questions**

What do you think of medicinal nicotine as a harm reduction product?

In your view, would a harm reduction approach based on getting smokers to use medicinal nicotine instead of cigarettes be likely to work?

What are the pros and cons of medicinal nicotine?

## Citizens Council on Smoking and Harm Reduction

### Case study on snus

Snus is a moist smokeless tobacco product that is consumed by placing it under the lip for extended periods of time. It has been suggested that snus could be used as part of a harm reduction approach to tackling the problems of smoking. However, snus is a controversial product and, while there are positive things to be said for it when compared with cigarettes, the World Health Organisation has said that its effects on health are unclear. Sweden, which is strongly associated with snus due to a long tradition of use, is currently banned from exporting it to any other EU country.

On one side, there are researchers such as the American tobacco control expert Jonathan Foulds, who said in a 2003 study of the effect of snus on smoking and public health in Sweden:

*Snus is manufactured and stored in a manner that causes it to deliver lower concentrations of some harmful chemicals than other tobacco products, although it can deliver high doses of nicotine. It is dependence forming, but does not appear to cause cancer or respiratory diseases. It may cause a slight increase in cardiovascular risks and is likely to be harmful to the unborn fetus, although these risks are lower than those caused by smoking. There has been a larger drop in male daily smoking (from 40% in 1976 to 15% in 2002) than female daily smoking (34% in 1976 to 20% in 2002) in Sweden, with a substantial proportion (around 30%) of male ex-smokers using snus when quitting smoking. Over the same time period, rates of lung cancer and myocardial infarction have dropped significantly faster among Swedish men than women and remain at low levels as compared with other developed countries with a long history of tobacco use. Snus availability in Sweden appears to have contributed to the unusually low rates of smoking among Swedish men by helping them transfer to a notably less harmful form of nicotine dependence.*

On the other side are experts such as Gunilla Bolinder, who, as you will remember, used snus as an example when arguing against harm reduction on day 1. You will remember that she concluded that using snus could not be considered a safe alternative to smoking for several reasons:

**Medical**                      significant health risks compared to nonusers, i.e.

- Is addictive
- Can cause cancer
- Increases death rates in patients with heart attack
- Increases the risk of diabetes
- Causes foetal damage
- Causes local oral damage

...but on a lower scale than smoking

**Pharmacological** high addictive potential

**Therapeutic** a resignation to achieve longterm nicotine detoxification

**Ethical** the tobacco industries efforts to continue to recruit young new addicts

### Questions

What do you think of snus as a harm reduction product?

In your view, would a harm reduction approach based on getting smokers to use snus instead of cigarettes be likely to work?

What are the pros and cons of snus?

## Citizens Council on Smoking and Harm Reduction

### Case study on lung delivery, non-combustible aerosols

One of the biggest problems with most of the currently available medicinal nicotine products that could be used as part of a harm reduction approach (for example, chewing gum, transdermal patches, lozenges, nasal sprays and inhalers, is that none of them delivers the high arterial plasma, and presumably brain, nicotine concentrations that cigarettes deliver. This was pointed out by John Britton on day 1, as well as a number of other speakers. As John put it, those other products can help but don't give someone the same 'hit' that he or she gets from a cigarette.

For this reason, as Neal Benowitz - a Professor of Medicine, Psychiatry and Biopharmaceutical Sciences at the University of California, San Francisco – has said:

*Smoking researchers have believed for some time that a 'pure nicotine' pulmonary inhaler that would produce rapid absorption of nicotine into the blood stream, similar to that obtained from tobacco cigarette smoking, could be an important tool in the effort to reduce tobacco-induced disease. Such an inhaler used instead of a cigarette would eliminate exposure to the combustion products that are primarily responsible for disease, and might be an effective smoking cessation treatment.*

One such pulmonary (i.e. lung delivery) inhaler has been developed by the Aradigm Corporation. Its product is designed to:

- *Deliver cigarette-like concentrations of nicotine directly into the deep lung where it has rapid access to the arterial circulation that supplies blood to the brain, and*
- *Enable a staged reduction in nicotine plasma peak levels in order to break the addiction to nicotine.*

Although Aradigm's inhaler has not been specifically designed for use in a harm reduction approach, some have suggested, like Martin Jarvis, that:

*Nicotine products with an adequately rapid absorption profile, with sensory properties to permit secondary conditioning, and which are consumer-acceptable, have great potential for harm reduction.*

A big problem with novel products, however, is that, because they are so new, the claims made for them are often based on relatively little data. There is also the question of how acceptable they would be to potential users.

### **Questions**

What do you think of lung delivery inhalers as a harm reduction product?

In your view, would a harm reduction approach based on getting smokers to use lung delivery inhalers instead of cigarettes be likely to work?

What are the pros and cons of lung delivery inhalers?

## Appendix Two: Voting on the importance of considerations

### Considerations

- 1.The need to focus on getting people to quit/not start smoking
- 2.The need for education on nicotine’s effect on health (relatively harmless)
- 3.The difference between tobacco-based harm reduction products, e.g. snus, and pure nicotine harm reduction products, e.g. patches, gum, inhalers, etc.
- 4.The need for age restriction
- 5.The need for medical and behavioural support
- 6.Availability (i.e. where would harm reduction products be sold?)
- 7.The need for prescriptions for higher dose products
- 8.Value for money
- 9.The need for harm reduction products not to be attractive to young non-smokers
- 10.Quitting should be primary message
- 11.Affordability
- 12.Price relative to price of cigarettes
- 13.The need for regulation
- 14.The need for products to tailored to the end-user
- 15.Shared funding from NHS and pharma
- 16.The need for research into the long-term effects of NRT
- 17.The need for education that it is not the nicotine that kills but the other things

### Position 1 - harm reduction as a way to quit smoking and break addiction

Consideration	1s	2s	3s	4s	5s
1	13	6	3	1	0
2	1	4	0	0	3
3	0	1	0	1	0
4	0	1	1	0	1
5	1	5	5	5	1
6	0	0	0	0	0
7	0	0	1	0	2
8	0	1	0	2	3
9	2	0	1	0	5
10	6	3	7	0	3
11	0	1	0	2	1
12	1	0	2	1	0
13	1	2	3	2	1
14	0	0	2	4	0
15	0	0	0	0	0
16	0	0	0	3	0
17	3	4	3	7	8
	28	28	28	28	28

### Position 2 - harm reduction as a way to provide a less harmful alternative

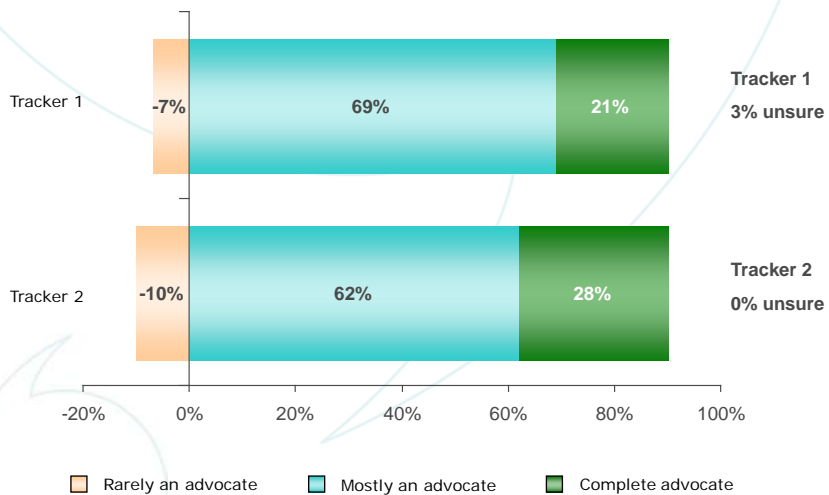
**to smoking while accepting that nicotine addiction continues**

<b>Consideration</b>	<b>1s</b>	<b>2s</b>	<b>3s</b>	<b>4s</b>	<b>5s</b>	
<b>1</b>	9	5	3	3	1	
<b>2</b>	3	2	1	0	2	
<b>3</b>	1	2	1	0	2	
<b>4</b>	0	0	3	1	1	
<b>5</b>	1	3	5	1	2	
<b>6</b>	0	1	0	2	2	
<b>7</b>	0	0	2	2	0	
<b>8</b>	0	1	0	1	3	
<b>9</b>	2	1	3	1	2	
<b>10</b>	4	6	3	2	1	
<b>11</b>	0	0	1	1	3	
<b>12</b>	0	0	3	2	1	
<b>13</b>	0	2	1	3	5	
<b>14</b>	2	2	2	3	2	
<b>15</b>	0	0	0	0	0	
<b>16</b>	1	0	0	4	1	
<b>17</b>	5	3	0	2	0	
	28	28	28	28	28	

## Appendix Three: Tracker questionnaire results



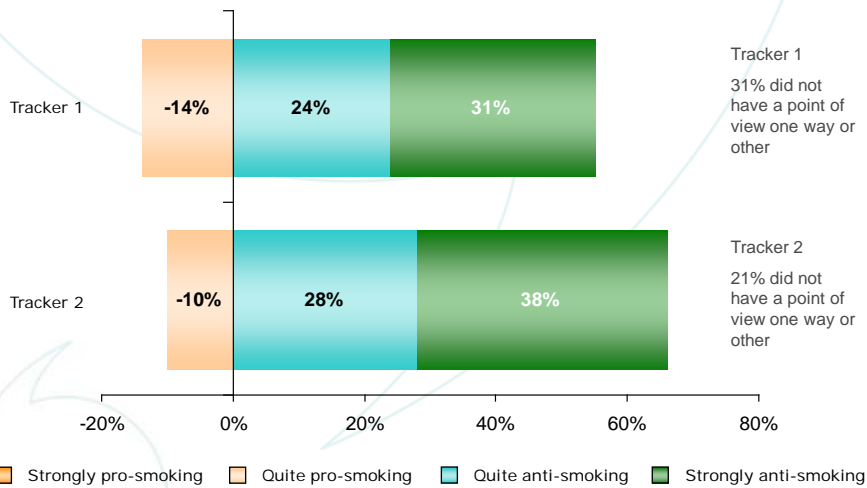
1: Thinking about what you know about NICE's work in general, to what extent would you consider yourself an advocate?



Current smokers: similar response rates to non-smokers

BASE: Tracker 1 n=29, Tracker 2 n=29

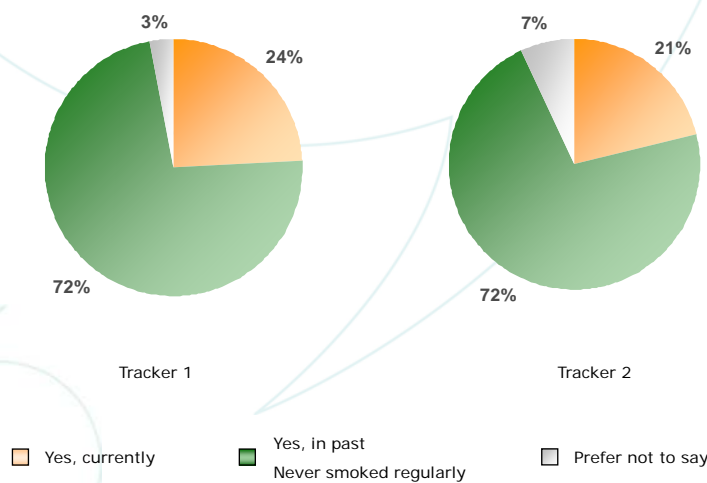
## 2: Which of the following best describes your point of view on smoking?



Current smokers: more likely to be quite pro-smoking / have no point of view – slight shift towards quite anti-smoking in tracker 2

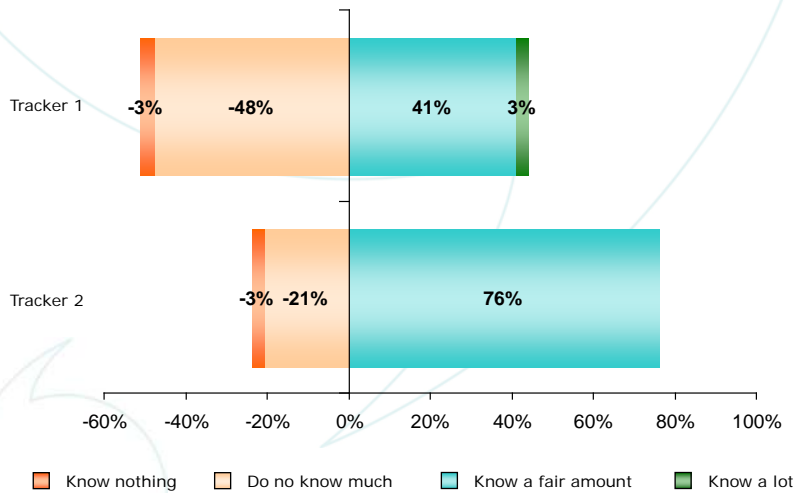
BASE: Tracker 1 n=29, Tracker 2 n=28

## 3: Do you currently smoke?



BASE: Tracker 1 n=29, Tracker 2 n=29

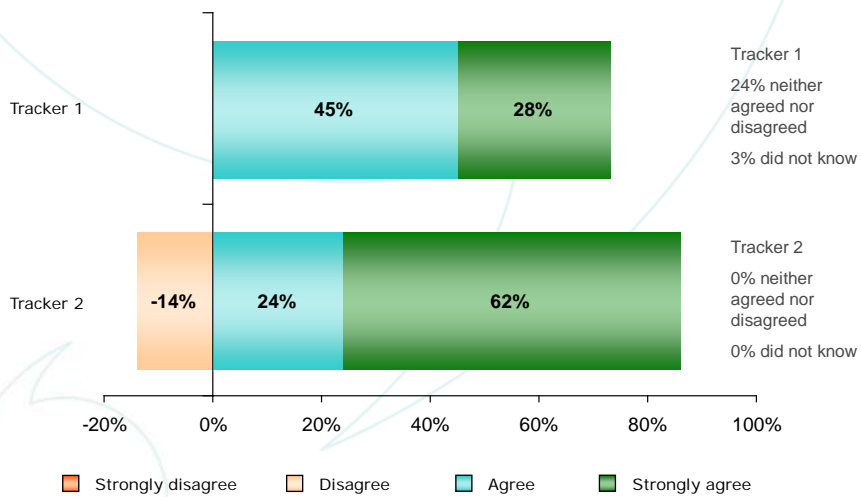
#### 4: How much would you say you know about current government / NHS policy relating to smoking?



Current smokers: more likely to say they know a fair amount about government / NHS policy

BASE: Tracker 1 n=28, Tracker 2 n=29

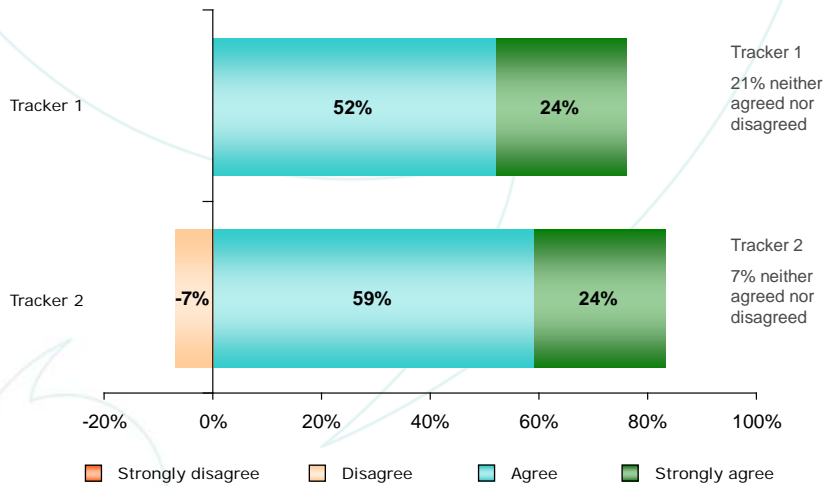
#### 5: Please indicate whether you agree or disagree that... a. The only way of reducing the harm done by smoking is by encouraging people to quit



Current smokers: similar response rates to non-smokers

BASE: Tracker 1 n=29, Tracker 2 n=29

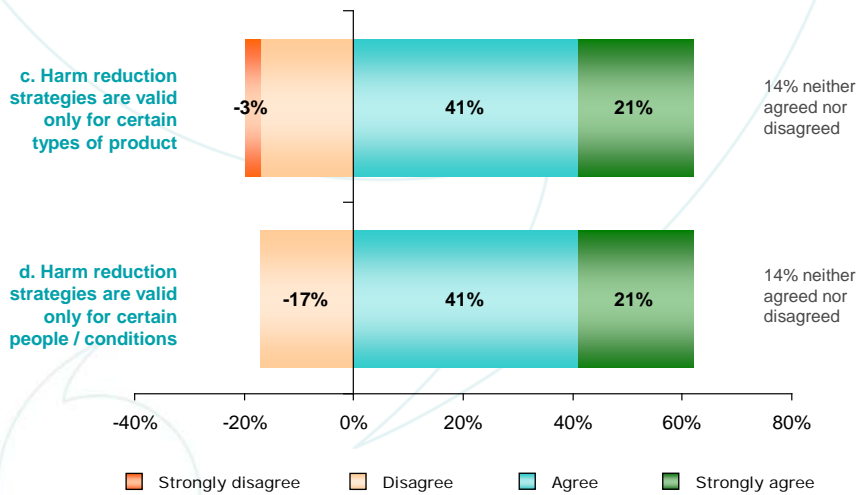
5: Please indicate whether you agree or disagree that...  
 b. Harm reduction is a valid strategy if it's not possible for people to quit e.g. encouraging alternatives to the more harmful products



Current smokers: similar response rates to non-smokers

BASE: Tracker 1 n=28, Tracker 2 n=28

5: Please indicate whether you agree or disagree that...  
 (Tracker 2 only)



Current smokers: similar response rates to non-smokers

BASE: Tracker 2 n=28 (c), n=27 (d)

**6: The most important factors for NICE to consider when making recommendations about reducing the harm done by smoking are...**

Rank Order	Factor	Tracker 1 (average rank)	Tracker 2 (average rank)
1	The best health outcome for largest number of individuals	1.2	1.3
2	Cost to NHS	2.3	2.8
3	Consideration of particular conditions	3.5	3.8
4	Risks and safeguards	3.9	3.9
5	Achieving a smoke-free society	4.5	4.2
6	Consideration of particular products	4.6	5.4
7	Who the manufacturers are	6.6	6.1

Current smokers: rank consideration of particular products above achieving a smoke-free society

BASE: Tracker 1 n=29, Tracker 2 n=29

**7: In your view, what is the best way to address the health risks that smoking presents to individuals**

	Tracker 1	Tracker 2
1	Education - On health risks of smoking - In schools / targeting the young	Education - On health risks of smoking - In schools / targeting the young - About harm caused by smoke vs. nicotine
2	Increased messaging / advertising - Stronger, more shocking messages on risks	Increased messaging / advertising
3	Provide alternatives to smoking - Harmless cigarettes	Encourage people to quit as priority
4	Limit smoking in public places	Provide assistance and support to smokers
5	Encourage people to quit as priority	Provide alternatives to smoking - NRT
6	Increase taxation of cigarettes	

BASE: Tracker 1 n=17, Tracker 2 n=20