

Harm reduction: an introduction to the issues

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What is harm reduction?

The term harm reduction refers to various strategies and approaches for reducing the physical and social harms associated with risk-taking behaviour. Examples include needle exchanges, purity standards for alcoholic beverages, safety glass in vehicle windscreens, driver air bags in high powered motor vehicles, and offering contraception to girls under 16. It may be impossible to prevent the harmful behaviour in all cases, but it may be possible to reduce the harm done. In the case of tobacco, harm reduction strategies are designed to reduce the harm to those who are unable or unwilling to stop using nicotine and involves a product and regulatory approach that supports (or does not inhibit) users switching to less harmful forms of nicotine. The US Institute of Medicine¹ uses the following definition: “a product is harm -reducing if it lowers total tobacco related mortality and morbidity even though use of that product may involve continued exposure to tobacco related toxicants.”

Underlying behavioural model

The underlying behavioural hypothesis is that tobacco use is a means of administering nicotine and that nicotine is addictive, causing users to modify their behaviour to attain their desired nicotine ‘hit’. The idea in a harm reduction approach is to separate the addictive behaviour from the harm caused by the nicotine delivery system and look for ways to reduce the impact of the delivery system.

What harm reduction approaches are available for tobacco?

Harm reduction strategies may be classified by the type of use, by the product used, or both. Saul Shiffman will be presenting a more systematic framework for categorising harm reduction options at the seminar, but here are some examples

Type of use	<ul style="list-style-type: none"> • Temporary abstinence from smoking • Reduced toxic exposure by taking nicotine in a way other than smoking tobacco • Reduced smoking due to taking nicotine from other less hazardous sources • Switching to nicotine that has a less dependency forming nature • Reduction of harm caused by ETS taking nicotine without smoking • Reduced fire risk
Type of product	<ul style="list-style-type: none"> • Cigarettes with reduced toxins in smoke – these might offer risk reduction of a few percent to perhaps 30% • Smokeless tobacco in several forms probably 10 to 100 times less hazardous than cigarettes • Medicinal nicotine – for example NRT – for which the harm is very small. • Future nicotine devices that might be produced should there be a market for them

The Health Development Agency has commissioned a literature review on the health impacts of smokeless tobacco, which will be presented at the seminar by its author Julia Critchley. There are also false harm reduction options – most notoriously this means the marketing of ‘light’ cigarette, but also to an extent the use of filters and probably the government policy of tar yield reduction.

Options for promoting harm reduction

There are many possible policy levers available to encourage harm reduction, and different levers

¹ Institute of Medicine, [Clearing the smoke: assessing the science base for tobacco harm reduction](#). Washington DC, 2001 ([Executive summary: page 2](#))

could be used for different approaches. These include the tax system, new indications for pharmaceuticals, packing and consumer information, lifting bans on smokeless tobacco, incentives for R&D, government funded research programmes that clarify and quantify the benefits or harm, education and awareness, setting mandatory performance standards for toxic emissions and ingredients in tobacco products.

What are the main conflicts?

Though harm reduction is well established in many areas of health policy, in the tobacco field it is often highly controversial. In determining whether and how to pursue harm reduction there are several important conflicts that must be addressed.

Drug use versus harm

For some there is an in-principle objection to drug-use and they see nicotine use as the main problem – deal with nicotine drug use and the harm reduction follows. The other view is that nicotine use has been in society for millennia and likely to persist for the foreseeable future. There is a wider liberalising attitude to drugs *per se*, with increasing concern about harm to users. They argue that focus should be dealing with harm caused by drug use both through complete cessation and through harm reduction strategies.

Harm reduction versus cessation

Some see harm reduction strategies as a distraction from quitting that blurs the message and in any case leaves users still exposed to harm (for example oral cancers associated with smokeless tobacco) and addicted to nicotine. They argue that what is needed is more resources devoted to quitting and that harm reduction strategies are a premature admission of defeat. Others argue that there are still 13 million tobacco users in the UK, that cessation rates are low, nicotine highly addictive and that tobacco use appears deeply rooted in some communities (for example in deprived communities or those with mental health problems) – they would claim that offering hooked smokers a choice of “quit or die” is irresponsible and unrealistic in real life. They stress that there are excessive risks associated with maintaining the status quo of pervasive cigarette use for nicotine delivery and that opponents of harm reduction should take responsibility for those too.

Intended versus unintended consequences

There is great concern that the outcome might not be the one expected and that unintended consequences will undermine the strategy. The opposing view argues that by not offering harm reduction options there may be many smokers that continue to use nicotine in its most hazardous form – cigarettes – and that is also an unwanted outcome. A particular problem here is that the balance of intended and unintended consequences is impossible to assess in advance and may be determined by whatever programme is used for a harm reduction strategy. Here are examples:

Intended or desirable consequences	Unintended or undesirable consequences
<ul style="list-style-type: none"> • Reduced harm to people that would have otherwise continued as regular smokers • Reduced harm arising from ETS exposure. • Possible ‘halfway house’ to cessation • Creates a market incentive for ever-better products to replace cigarettes 	<ul style="list-style-type: none"> • Extra harm caused to people that might otherwise have quit completely • Potential for young people to start with the harm reduction option believing it to be safer (a ‘gateway’ theory) • Potential for ex-smokers to relapse to the harm reduction option – then to smoking.

Quantitative versus qualitative view (risk-use equilibrium)

For some, the likelihood of unintended consequences is sufficient reason to oppose such measures. Others argue that it is essential to attempt to quantify the balance of advantage and adversity. If millions of smokers greatly reduce their risk by switching to say smokeless tobacco and a few ex-smokers take up smokeless tobacco then it is likely that the total population public health has been served well on balance. If on the other hand, a small reduction in cigarette toxicity is aggressively marketed to reassure smokers (as with ‘lights’) then maybe the effect of reduced

quitting would overwhelm any benefits. This balancing of risk and use has been formalised in Kozlowski L. et al. (2001)² to show that there are no plausible circumstances in which wider use of NRT for harm reduction could lead to the unintended consequences overwhelming the benefits. The same analytical approach, though perhaps with entirely different conclusions, may be applied to other harm reduction strategies. Lynn Kozlowski will be presenting on the risk/use equilibrium concept at the seminar.

'Public health master-planner' versus human rights of smokers

How much should benevolent and expert policy makers try to make decisions for people, hopefully acting in their best interests? How much should users be able to make their own decisions? A concrete example of this dichotomy is the ban on many forms of smokeless tobacco in the European Union. Some smokers could switch to that and do themselves much less harm, but the authorities have decided not to allow that option, believing that there are other risks that are more important. Does that infringe the rights of smokers? What if the policymakers are wrong? Some argue that the unpleasantness of withdrawal is an important driver of cessation, and that smoke-free policies as well as de-normalising smoking encourage quitting by inflicting withdrawal on smokers. But does a regulator infringe human rights if they ban a product that would relieve withdrawal symptoms during temporary abstinence? If a smoker switches to smokeless tobacco or wears an NRT patch while driving his family around, he may lose painful feelings of guilt about his kids, and their health may be improved. Is it right to deny those benefits to this individual because of concern about unintended consequences arising elsewhere? Lynn Kozlowski has developed excellent arguments on the 'rights' concept, and will be presenting these at the seminar.

Profiteering versus challenging Big Tobacco

Some are concerned that this is just a way of regularising a drug business in the interests of Big Business (whether tobacco or pharmaceuticals). Everyone in public health is united in concern that the tobacco industry will exploit harm reduction and put profit ahead of people. The danger of attacking say, smokeless tobacco or wider use of medicinal nicotine, is that it plays into the hands of BAT and Philip Morris consolidating the hold of the cigarette on the nicotine market. Those favouring harm reduction strategies argue that if a business can make money by challenging the worst forms of nicotine delivery, then they will do it more effectively and their threat to the entrenched tobacco barons will be greater.

Markets versus regulation

Harm reduction options could be introduced onto the market as part of a battle for market share – aiming to capture the niche of smokers sufficiently concerned about their health to be prepared to change products. Some say that the issues are so complex and the risks so serious that harm reduction options can only be introduced under a strict regulatory regime – perhaps like the regulation of pharmaceuticals. However, what should happen if such a regime is not forthcoming? Some argue that it is perverse and distorting to press for rigid regulation of the harm reduction options while tolerating virtually no regulation for the most hazardous options. Should harm reduction be absolutely conditional on a pervasive regulatory regime? Is there a risk that regulatory hurdles will be piled up so high that the approach will never work in the real world – thus abandoning the nicotine delivery market to cigarettes – which would also not be regulated? Some argue that a mixture of regulation and market-based initiatives might be a more pragmatic and effective approach – and that this should be extended to the existing cigarette market. The analogy might be with vehicle safety where there are mandatory standards for windscreen glass, steering column collapse, fire hazards etc, but also safety features offered as optional in the market – like anti-lock brakes and air-bags.

Precautionary versus evidence-based

Some argue that no interventions should be made or policies changed unless there is solid evidence to back them – if possible randomised controlled trials. However, gathering the evidence for the effectiveness of a harm reduction strategy may take decades, and would require a strategy

² Kozlowski L. et al. Applying the risk/use equilibrium: use medicinal nicotine now for harm reduction [Tob Control 2001;10:201-203](#)

to be in place in order to measure its effects. Demanding incontrovertible evidence may amount to a *de facto* block on any progress in this area. Others would point out that there is no good evidence to justify maintaining the status quo either, and that *not* acting also has consequences that cannot be measured. They would claim that in this area, as in any other policy, it is a matter of judgement informed by what evidence there is with whatever analytical tools techniques are available – with efforts made to monitor and correct policy as a programme proceeds.

Resolving the conflicts

The purpose of the seminar is to consider and explore these conflicts and to move towards a common understanding or approach – or at least to understand where there are differences of opinion and why these are held. One way forward may be to use ‘SWOT analysis’ look at the Strengths, Weaknesses, Opportunities and Threats associated with three main approaches. Here is a first attempt that could be developed through further discussion at the seminar:

1. Reduced toxins from cigarettes - omni, advance, eclipse etc

Strengths	Likely to reach the most users and have greatest consumer acceptability as this is the closest to conventional cigarettes
Weakness	Risk reduction likely to be small, reasonable health claims very difficult to make and verify.
Opportunity	Small change in harm to continuing cigarette smokers – but could apply to many users if imposed as regulatory standard.
Threat	False or misleading marketing claims and the new 'lights' - false reassurance to smokers and reduced quitting or increased relapse. Could be seen as a starter cigarette.
Possible approach	Introduce product modifications of this nature through setting mandatory performance standards for all smoked tobacco products or cigarettes. Do not allow claim-making, including false claims such as ‘lights’.

2. Oral tobacco – Swedish snus, Ariva

Strengths	Good consumer acceptance on account of tobacco characteristics, combined with very substantial reduction in risk (10-100 times) including complete elimination of ETS.
Weaknesses	Change may be too great for many smokers. Health risks remain and the means of communicating a reduced risk could be difficult.
Opportunity	Could provide a mix of deep harm reduction and reach many smokers
Threat	No standards may allow ‘dirty’ smokeless tobacco on the market, could be a gateway
Possible approach	Replace the ban in the EU with product quality standards - like Gothiatak , do not allow advertising, allow meaningful consumer information on the pack.

3. NRT for harm reduction rather than cessation

Strengths	Least harm to smokers no ETS - also least likely to cause dependence. High level of trust and an existing regulatory framework.
Weaknesses	Least likely to appeal as an alternative to smoking. Difficulties for pharmaceutical companies in entering this market
Opportunity:	Great reductions in harm and perhaps a ‘gateway’ to quitting through more familiarity with cessation products.
Threat	Continuing tobacco use instead of quitting due to reduced pressure to quit arising from use during temporary abstinence.
Possible approach	Needs liberalisation so that medicine regulation takes account of damage caused by smoking. Substantial off-licence use for harm reduction should be legitimised and marketing permitted