EDUCATION & DEBATE

Recent Advances

Tobacco control

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The nicotine patch is an important innovation in smoking cessation

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The world now has an estimated 1.1 billion smokers that is, about one third of the global population aged 15 years and over. Most of these smokers (800 million) live in developing countries. China alone has 300 million smokers (90% men), about the same number as in all the developed countries combined. About one third of regular smokers in developed countries are women, compared with only about one in eight in the developing world.¹

During 1990-2 smokers consumed some 6.05×10^{12} cigarettes per year,¹ with an estimated three million deaths annually, a figure which is expected to rise to 10 million a year by the 2020s or early 2030s. Seventy per cent of these deaths will occur in developing countries.²

With such huge numbers, advances in tobacco control worthy of the name must have potential to make major inroads into those factors that promote current rates of smoking. Otherwise they risk being marginalised as largely irrelevant to efforts to address seriously what is without doubt a global pandemic. The acid test of this relevancy has always been the litmus paper of reaction in the tobacco industry. If the industry opposes a tobacco control initiative, this is diagnostic of a policy that promises to bite hard into tobacco sales. If it applauds or ignores initiatives, we can feel certain that they are of little consequence. On this basis, several outstanding themes have emerged in recent years.

Tobacco taxation

Tobacco products have a price elasticity in Western nations of approximately -0.5, meaning that a 10% rise in price causes a 5% fall in demand.³ In recognition of this, tobacco companies regularly wage price wars with each other and are implacable in their opposition to rises in tax on tobacco. With smoking typically being more common in income groups with lower disposable income and evidence that cessation in low income groups is much more responsive to price rises than in higher income groups,⁴ price policy is widely considered to be of the highest priority among tobacco control strategists. Given the lack of resources and infrastructure devoted to tobacco control in most developing countries, price policy holds enormous but largely unexplored potential as a cost free means of reducing demand.⁵ However, because cheaper, "tax unpaid," smuggled cigarettes are widely available in many developing nations,6 tax policy may not prove to be as feasible in such countries.

Regulation of tobacco

Historically, all nations have treated tobacco as if it were a simple grocery item, with minimal regulation often applying to its availability, packaging, and advertising. In the United States the Food and Drug Administration has proposed to regulate tobacco as a drug delivery device⁷ and has consequently been the

Summary points

• With one billion smokers consuming 6.05 trillion cigarettes annually, successful tobacco control strategies must have the potential to reduce such numbers substantially

• Reactions of the tobacco industry to control strategies serve as a litmus test of potential effectiveness

• Tobacco products have a price elasticity of -0.5 (a 10% rise in price causes a 5% fall in demand). Taxing tobacco is a low cost strategy with great potential to reduce consumption among smokers in low socioeconomic groups and in developing countries

• The efforts of the United States' Food and Drug Administration to regulate tobacco as a drug delivery device promise to revolutionise government approaches to tobacco

• Evidence now exists that children are the most responsive market segment to tobacco advertising

• Banning smoking at work can reduce daily smoking in continuing smokers by 25%—an unprecedented degree of impact

• Harm reduction policies are likely to become hotly debated in nations where the decline in smoking has stalled

• Legal actions against the tobacco industry by state governments in the United States have begun to rend cracks in the hitherto impenetrable wall of defence by the tobacco industry

• Active monitoring and prosecution of shops that sell tobacco to children can dramatically reduce sales to children, but further research is needed on whether these actions reduce tobacco use by children

target of an unprecedented lobbying campaign by the tobacco industry.⁸ The administration's recommendations are being strongly supported by President Clinton. If legislation goes ahead, it will allow (by other national standards) the modest regulation of tobacco advertising and access by minors. The real implication of this development, however, lies in the Pandora's box of possibilities that will open both for the United States and for other nations in areas such as generic (plain) packaging,⁹ full disclosure of additives, and serious restrictions on the number of retail outlets.

Tobacco advertising and promotion

There are encouraging signs of substantial momentum in the hitherto glacial acceptance by governments that tobacco advertising is of critical importance in influencing children to start smoking and in the willingness of governments to act to control advertising. Several Asian nations, including China, have recently implemented new restrictions on tobacco advertising. The tobacco industry has had considerable success with its strategy of arguing that, unlike every other industry, its advertising is not directed at recruiting new consumers. The poverty of this argument has recently come under further pressure from recent research showing the greater responsiveness of children than current smokers to advertising.¹⁰⁻¹²

Over 100 nations now restrict tobacco advertising to some degree.¹³ In recent years Australia, New Zealand, and Canada have introduced all but total bans on tobacco advertising, exempting point of sale advertisements. Canada's ban was overturned by the High Court in 1995 but is expected to be reintroduced when the government reclassifies tobacco as a restricted product, subject to the same sort of controls as pharmaceuticals.

In the United States, Philip Morris, the world's largest tobacco company, has offered to cooperate with one of the Food and Drug Administration's recommendations that tobacco advertising should not be sited within 1000 feet (300 m) of schools or playgrounds.¹⁴ The amusing logic here—that a billboard at 999 feet could influence children but at 1001 feet would be benign—is none the less of symbolic importance as an industry admission that tobacco advertising can influence children.



Historically, minimal regulation applied to advertising of tobacco

Major concern remains about the potential of satellite television to deliver tobacco advertising to international audiences. National laws on tobacco advertising may become historic irrelevancies in the era of satellite communication.

The Trojan horse of passive smoking

Concern about the effects of passive smoking on the health of non-smokers has widened the tobacco debate fundamentally from "my smoking is dangerous to my health" to include "your smoking is dangerous to my health," thereby transforming the ethical justification for smoking control policies from paternalism to Millian precepts.15 The implacable worldwide efforts by the tobacco industry to discredit the epidemiological evidence on passive smoking and to support "smokers' rights" movements¹⁶ is explicable in terms of the loss of sales caused by smoking bans.¹⁷ When people cannot smoke at work their daily consumption falls by up to 25% ¹⁸ ¹⁹—a level unprecedented in any other intervention. Cessation is also promoted by workplace bans.²⁰ As smoking bans in the workplace and on public transport proliferate,²¹ the number of cigarettes forgone will correspondingly increase.

Harm reduction

Other areas of drug policy have long embraced a harm reduction philosophy, where population-wide goals of "zero use" are seen as largely unrealistic, obviating the need for policies that can at least reduce harm. By contrast, international tobacco control has always been dominated by absolutist precepts, where slogans such as "no safe level of use" have assumed inviolate status. Those supporting this position argue that policies that in any way facilitate reduced tobacco use are both dangerous and naive distractions from policies that are cessation oriented. This absolutism has tended to dampen enthusiasm for policies that reduce either smoking or the delivery of harmful tobacco constituents to smokers. This debate seems certain to be tested by the development of new tobacco products such as Eclipse-a largely smokeless cigarette that delivers carbon monoxide and vaporised nicotine to the smoker, but not tar.²² R E Reynolds, Eclipse's manufacturer, has sought dialogue with the tobacco control community, resulting in considerable debate between absolutists and those who are more pragmatic. Critics of this development point to the market failure of similar prototypes and caution that tar free cigarettes may serve merely to divert smokers from stopping smoking, maintaining nicotine addiction before likely reversion to routine cigarette smoking. With evidence from several nations that the decline in adult smoking has stalled, the harm reduction debate is likely to increase, with many challenging questions arising for researchers about reducing the risks for continuing smokers.

Nicotine replacement therapy

Nicotine gum and patches are now widely regarded as important innovations in smoking cessation, with meta-analyses finding rates of cessation in users in a variety of settings that are two to three times higher than with placebo or no nicotine replacement therapy.^{23 24} With several countries now ending the prescribing monopoly and rescheduling nicotine replacement therapy to make it available over the counter, higher rates of use are expected because of easier access.²⁵ Rescheduling can also allow nicotine replacement therapy to be advertised to the public, leading to the broadcast and publication of many more motivational messages about cessation. Important research questions will arise about the comparative skills of physicians and pharmacists in counselling smokers about cessation.^{26 27}



The shop that sold cigarettes to these children could be prosecuted

Legal actions

The 1990s will be remembered in the history of tobacco control as the decade when legal actions against the tobacco industry became turbocharged with state initiated actions, private class actions, and personal injury lawsuits. These include:

• Seven US states suing tobacco companies for recovery of health care Medicaid costs in treating diseases caused by tobacco in the indigent (one tobacco company, Liggett, has agreed to pay 5% of pretax income—to a maximum of \$50m (£33.3m) a year—for 25 years²⁸);

• A Florida class action on behalf of non-smoking current and former flight attendants who assert that they have diseases caused by their exposure to tobacco smoke in aircraft cabins;

• The Castano class action—a case filed by a consortium of 60 prominent American law firms on behalf of "all nicotine-dependent people in the United States...who have purchased and smoked cigarettes manufactured by the defendants." The case focuses on addiction and is based on recent statements by the Food and Drug Administration's commissioner, David Kessler, that tobacco companies intentionally sell cigarettes with an addictive level of nicotine.^{29 30} The plaintiffs claim that tobacco companies manipulate the level of nicotine in cigarettes so that it is addictive and allege that the defendants engaged in, among other things, fraud, deceit, negligent misrepresentation, and violation of consumer protection statutes.

Whistleblowing and leaks

In the past two years the United States has seen an unprecedented series of whistleblowers come forward from the tobacco industry with both extensive documentation³¹ and testimony ³²⁻³⁴ covering the industry's knowledge and tactics on health effects, nicotine addiction, passive smoking, and marketing strategies. Whatever the outcome of the legal testimonies of these individuals in the various cases to which they are contributing, their revelations have caused huge and unprecedented negative media coverage about the tobacco industry, from which the industry is unlikely to recover politically.

Action on sales to children

Like adults, most children obtain their cigarettes from shops.³⁵ Until recently, the policy implications of

this have been virtually ignored by tobacco control strategists, who for the most part have used educational strategies directed at reducing demand, with generally disappointing results.³⁶ However, a recent research emphasis on the ease with which children can purchase cigarettes has translated into the adoption of "compliance monitoring" strategies-that is, supervised children try to buy cigarettes and those shops found to be selling to the children are often prosecuted.³⁷ Dramatic falls in selling rates have been reported after these monitoring exercises,³⁸ although good evidence is not yet available that reduced access to purchasing leads to reduced use. Concerns also exist that most of the studies have been conducted in isolated towns in the United States, where children cannot travel to neighbouring suburbs to buy cigarettes as they could in city locations. None the less, the promise of these studies has inspired the passage of the Synar amendment in the United States, whereby federal funding for state substance misuse programmes is partly conditional on states demonstrating that they have met reduction targets in tobacco sales using compliance monitoring targets.

Despite huge advances in tobacco control policy, and substantial reductions in adult smoking, smoking among young people is rising in the United States,⁴⁰ Canada,⁴¹ Britain,⁴² and Australia,⁴³ all of which have histories of strong commitment to tobacco control.

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Lesson of the Week

Anabolic steroid abuse by body builders and male subfertility

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Abuse of sex steroids by recreational body builders may be an unrecognised cause of infertility Steroid abuse by a minority of top class athletes is well recognised. Abuse by competitive body builders is thought to be common but has caused less public concern. Recreational body builders attending gymnasiums also abuse steroids¹ but the frequency and patterns of use and the associated problems are less well known.

Among other side effects androgenic steroids induce hypogonadotrophic hypogonadism with subsequent azoospermia.² Over the past year we have noted an increased number of men attending the infertility clinic who have been using anabolic steroids for body building. This has been associated with an apparent substantial increase in body building as a recreational pastime in the north east.

We are concerned about the lack of understanding of the consequences of steroid use by users and providers and the ease with which the diagnosis can be missed. The following five cases illustrate the problems.

Case reports

Case 1-A couple (husband aged 29) requested in vitro fertilisation after primary subfertility for three years. Results of two semen analyses arranged by the general practitioner in early 1994 were normal (sperm densities 80×10° and 150×10%). At presentation the husband was severely oligospermic (sperm densities nil and <100×10⁶/l). His hobby was weightlifting and he admitted to taking oral steroids for two weeks 12 months earlier. Examination showed a normal muscular male physique with normal secondary sexual characteristics. However, follicle stimulating hormone and testosterone concentrations were very low, confirming steroid use. He admitted to taking a "protein health drink" which was made up by the gymnasium before training. Three months after stopping this drink his sperm density was 100×10%/l.

Case 2-A couple (husband aged 35) were referred for in vitro fertilisation with donor sperm. The husband owned a gymnasium and his hobby was body building. At the age of 24, six months after mumps without testicular involvement, a semen sample had shown azoospermia with maturation arrest on testicular biopsy. They were referred to a large tertiary referral unit. Knowing he was azoospermic from an apparent other cause, the husband had started and continued to take anabolic steroids without informing anyone.

Azoospermia was confirmed and they received unsuccessful donor insemination. He stopped steroids at the age of 31 because of fear of the general side effects at that age. Four years later routine semen assessment before in vitro fertilisation showed normal sperm densities (90×10° and 59×10°/l). For several years they had almost abstained from intercourse because they thought they had no chance of conceiving naturally.

Case 3-A couple (husband aged 28) attended for investigation of secondary subfertility for 12 months. Each had a child from a previous relationship. The husband was azoospermic. He admitted to body building and regular use of oral testosterone from 1990 to September 1994. In an attempt to reverse the effects of the steroid "treatment" he was given human chorionic gonadotrophin injections by the supervisors of the gymnasium that he attended. His wife was unaware of the drug abuse. Five months after stopping steroids his sperm density was 30×10⁹/l.

Case 4-A couple (husband aged 27) had primary infertility for over two years. The husband had been a body builder since the age of 18 because of bullying. He had used steroids from the age of 21 but stopped 10 months before the consultation. Semen analysis results were: January 1995, 1.9×10% (99% motile); June 1995, 11×10% (16% motile); September 1995, 14×10% (36% motile). He provided a detailed list of the oral and intramuscular drugs that he had used (needles being obtained from the needle exchange programme). These were: 1987 methandienone (Dianabol; six months); 1988 methandienone (Dianabol; four months), nandrolone (Deca-Durabovan), and intramuscular methyltestosterone (Testoviron; three to four weeks); 1990 oral mesterolone (Pro-Viron; two years) and oral stanozolol (Stromba); 1992 intramuscular methenolone (Primobolan; six months on, six months off) and oral nandrolone (Anabolin); 1993 oral methenolone (Primobolan; one year) and testosterone propionate (Testex; three months on, three months off for one year); 1994 intramuscular stanozolol (Stromba) and oral methandienone (Dianabol). He stopped the drugs in May 1994.

Case 5-A couple (husband aged 28) presented with two years of primary infertility. The husband attended a gymnasium regularly for recreation and weight training. For five months before presentation he had taken steroids given to him by friends at the gymnasium. He doubled the dose that his friends suggested. His sperm

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