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Tobacco Dependence Treatment in England

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Introduction

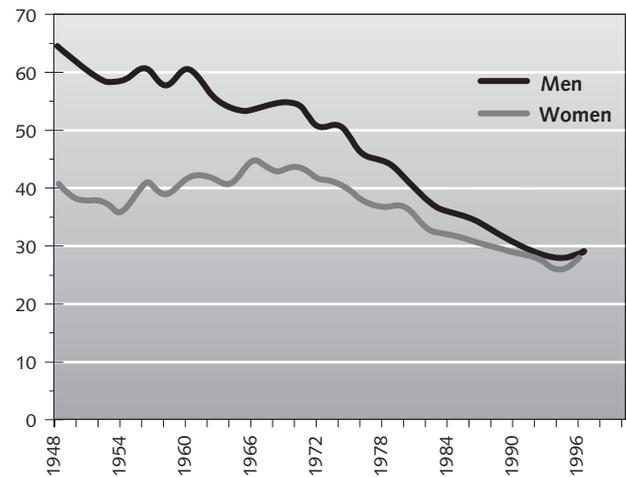
In England¹ (as in the United Kingdom of Great Britain and Northern Ireland as a whole) smoking prevalence in adults (aged 16 and over) has been falling in both men and women since the 1970s (1). During the 1990s, however, this decline levelled off, as the diagram below illustrates. Currently, in England 27% of adults smoke – 28% of men and 26% of women. Over the last 20 years there has been a similar trend in 11–15-year-olds, in whom prevalence has fallen only very slightly. In 1982, 11% of 11–15-year-olds were regular smokers (defined as at least one cigarette a week on average), 11% of boys and 11% of girls. In 1999, the figures were 9%–8% of boys and 10% of girls (1).

There are currently about 13 million smokers in Britain (2) and a large socioeconomic gradient: 15% of professionals smoke compared with 39% of unskilled manual workers (1). This gradient has become steeper as more professionals have stopped smoking. There is also evidence of higher dependence within the more deprived smokers (3). Most smokers (82%) start as teenagers and most – about 70% in Britain (see footnote) – say they want to stop (1). Even among those who want to stop, the unaided cessation rate measured at one year is less than 5% (4).

In the United Kingdom of Great Britain and Northern Ireland more than 120 000 people a year are killed as a result of smoking, mainly through lung cancer, chronic obstructive pulmonary disease and coronary heart disease. This represents one in five of all deaths (1.2). Half of all lifelong smokers are killed by their smoking in middle age (35 to 69 years), and the average loss of life is 15 to 20

Figure 1

Adult smoking prevalence in England (per 100)



years (5). The total annual cost of smoking-related disease to the national health service (NHS) in England is from about £1,500 to £1,700 million a year (about US\$ 2,250 to US\$ 2,550 million; all dollar conversions at £1 = \$US 1.5) (6).

The historical context: development of policy on tobacco control and on treatment within it

The development of a policy to treat dependent smokers in the United Kingdom should be seen in the context of the development of tobacco control as a whole, which was a lengthy process. Doll & Hill's first report, in 1950, linking the increase in lung cancer to smoking (7), planted the seed. Their work led to the establishment of the British doctors' study, a long-term cohort study that is still yielding data now on smoking death rates. In 1962, Charles Fletcher persuaded the Royal College of Physicians (RCP) to publish their first report on smoking and health (8), and this was really the beginning of the tobacco control campaign in Britain. Disappointed by the lack of political action following the report's publication, the college published a second report in 1971 (9) and, perhaps more significantly, created the organization Action on Smoking and Health (ASH), which appointed its first campaigning director in 1973. The Government set up the Health Education Council (later called the Health Education Authority (HEA), then the Health Development Agency) in 1967, so that by the mid-1970s, a decade after the first RCP report, there were governmental and nongovernmental bodies campaigning on smoking and health. However, progress

¹ The data and events described in this paper are from England unless otherwise stated. Government policy on smoking, and its 1998 White Paper (2) apply to the whole of the United Kingdom of Great Britain and Northern Ireland (England, Scotland and Wales and Northern Ireland) have implemented a broadly similar policy on treatment for smokers. However, the countries have slightly different healthcare systems and the authors' main experience and involvement has been in England, so this article has focused on the situation in there. This is also why over the years survey data have not consistently been available for one country and so have sometimes been drawn from England, and sometimes from Britain and the United Kingdom.



was slow. In 1984 the British Medical Association (BMA), which represents about 90% of all British doctors, added its influential voice to the campaign (10). During the 1980s, one of the main focuses of the campaign was an advertising ban. This was unsuccessful but during this period governments started using increases in taxation to raise revenue, and later (explicitly) to reduce smoking prevalence. It could be said that by the 1990s, 30 years after the campaign began, the Government officially accepted the harm caused by smoking and the goal of minimizing this harm. Also during the 1990s an increasing role was being played by the HEA, which built up and contributed to expertise in tobacco control.

While extremely important, none of these developments in itself directly advanced the case of treating tobacco dependence. Tobacco dependence was not widely recognized as an addiction until the 1990s (the United States Surgeon General's report on nicotine addiction was published in 1988 (11)). Some in the health education field in Britain felt it was more important to concentrate resources on mass population approaches to persuading smokers to stop, rather than on a minority of nicotine addicts who needed help. In effect, smoking was seen as an educational issue, the key task being to persuade smokers that they should try to stop. Such mass population approaches are important. Because of their wide reach they can trigger quit attempts, and cessation, on a massive scale. They are also an important precursor to helping smokers stop since they create the demand for this help, by increasing motivation to stop. Treatment services are unlikely to be feasible in a country that does not have a broader tobacco control campaign, since there may not be enough smokers motivated to stop. By the same token, once there is greater motivation to stop smoking in a population, it then becomes clear that many smokers are addicted to nicotine and need help in stopping. The statistics quoted above remind us of this: about 70% of smokers in England want to stop, and the unaided cessation rate is less than 5%.

It was during the 1990s in Britain that treatment of dependent smokers finally became accepted as an important activity in its own right. One occurrence that influenced this was the parallel development of research on tobacco addiction, the best-known national centre in Britain being the Addiction Research Unit in London, part of London University, which during the 1970s and 1980s was supported by large programme grants from the Medical Research Council. The relatively long duration of the funding was important, because it allowed the

progress over several decades of a team of researchers, which resulted in pioneering research on nicotine addiction, the role of the general practitioner (12), behavioural treatment and groups, and nicotine replacement therapy (13), *inter alia*. Furthermore, many of the group, led by Michael Russell, remained in the field after leaving the Addiction Research Unit and contributed to the continuing evolution of treatment policy and research, from universities, the health service, and a national governmental organization.

Thus, by the mid-1990s, in Britain there was a strong tobacco control coalition. It was led (informally) by the campaigning organization ASH, supported by expertise from the HEA (that funded supporting projects and research), which included medical and other health professionals, and university-based treatment specialists and researchers developing the evidence foundation. The ground was fertile. All these strands were brought together following the election in 1997 of a new Government, which promised concerted action against tobacco, including an advertising ban and a tobacco "White Paper" – a formal Government policy paper (2).

During 1997, while the Government was writing the White Paper, the HEA commissioned the first English smoking-cessation guidelines. These guidelines played a large part in shaping Government policy as a result of the interaction among the cessation researchers writing them, the HEA director who managed the project and a key official in the Department of Health. New treatment services were written into the White Paper.

Three key concepts were also vital in persuading the Government of the importance and value of treatment to help dependent smokers stop: that smoking is an addiction (4), (11), (14), (15), that treatment is effective (16), (17), and that treatment is cost effective (6). It was important to emphasize that many smokers are nicotine addicts who need and deserve help from the health care system. This fact is underscored by the classification of nicotine addiction/tobacco dependence as a disease by the World Health Organization's ICD classification (14) and by the American Psychiatric Association's DSM-IV classification (15). Within Britain, the Royal College of Physicians report *Nicotine Addiction in Britain* (4) was significant, again illustrating how influential medical professional bodies can be.

The effectiveness and cost-effectiveness evidence were also important in demonstrating that money spent by the health care system helping smokers stop is extremely well

spent. When the national cessation guidelines were first published, guidance on cost effectiveness was published with them. This guidance showed smoking cessation to be one of the most cost-effective interventions in the health care system. It produces one extra life year at a cost of less than £1,000, compared with an average cost of £17,000 from a review of 310 medical interventions (6). These data and arguments compelled key people, including those inside Government, to support a treatment policy. Since the treatment services were established, a new Government body, the National Institute of Clinical Excellence (NICE), has published its own assessment of the effectiveness and cost effectiveness of NRT and bupropion, which has added strong and authoritative support to the services (18).

The provision of new funding (see next section) – for educational measures *and* separately for treatment services – was fundamental in advancing the case of treatment. It had been argued in the past that scarce health education resources should not be ‘diverted’ from population approaches to treatment, which would not affect population prevalence. The new funding meant that educational approaches could continue, and that treatment could be offered by the appropriate sector – the healthcare system (as opposed to the health education sector).

Thus, after years of failing to recognize the needs of addicted smokers, a policy on treatment emerged within a wider tobacco control policy drawn up officially by the Government. The Government White Paper also crucially proposed a tobacco advertising ban, action on tobacco taxation, smoking in public places, under-aged smoking, smoking and pregnancy, and action against cigarette smuggling.

Chronology and implementation of new English treatment policy

The Government’s White Paper *Smoking Kills* was published in December 1998 (2). English national smoking cessation guidelines (16), along with guidance on cost effectiveness (6), were also published by the HEA, for the first time ever, in December 1998 and launched by the Public Health Minister in 1999. These guidelines were evidence based and formally endorsed by more than 20 professional organizations, including medical and nursing bodies. The Minister announced that approximately £110 million (about US\$ 165 million) would be made available for tobacco control in England, roughly half of this for new

treatment services. The new treatment services were to be developed over three years starting in April 1999. In the first year, £10 million (US\$ 15 million) would be spent in 26 selected “pilot” areas; areas especially chosen for their levels of social and economic deprivation. In April 2000 the services were extended to the rest of England, with a budget of up to £20 million (US\$ 30 million) for the first year, and up to £30 million (US\$ 45 million) for the second year. At the time it was not stated by the Government what would happen to the services when the funding ran out in March 2002. Services were advised to target priority groups, in particular socially disadvantaged smokers. In addition, in each year targets were set for the numbers of smokers who had received specialist support through the services and reported having stopped four weeks after their quit date. Because these targets were exceeded in years one and two, they were increased for the third year of services, and again for the (subsequently funded) fourth year.

Implementation of the new policy developed as more detailed guidance was provided by the Government and as problems were encountered. One problem that had negative consequences throughout the project was the short-term nature of the funding. Originally, the Government said that money for year two would depend on evidence of success from year one (2) – an unrealistically short time scale in the real world. In the third year of the project a lobbying campaign was launched to try to persuade the Government to announce further funding to continue the services, in order to prevent staff losses caused by short-term contracts (19). This campaign included a document written by experts and supported by professional bodies, the Department of Health, and the pharmaceutical companies, setting out the cost-effectiveness argument for treating smokers (20). This document illustrated the savings that could be made on other aspects of the health care system, such as statins (cholesterol-lowering drugs that reduce the risk of heart disease) expenditure, if smoking cessation interventions were a routine part of health care. It was produced with the support of the World Health Organization (WHO) Europe Partnership Project (21). At the end of 2002 one year’s extra funding – the fourth year – was announced, thus extending the project to March 2003.

Despite the formidable challenge of setting up a brand new treatment service nation-wide, progress was rapid. By the end of 1999, just 9 months after the official start of the new services, 137 new staff (mainly cessation



counsellors but also managers – many of whom were also cessation counsellors) in England were already in post. This was a remarkable achievement in such a short time, considering the need to move the money to the health service, advertise for new staff, appoint them, and train them. At the time of this writing (late 2002) the services have some 500 paid staff, with many more primary care professionals who have been trained to give smokers support as part of their wider work.

The Government spent £53 million (\$US 80 million) on the new services in their first three years (this does not include expenditure on pharmaceuticals) and up to £20 million (\$US 30 million) more in the fourth year, which is still in progress at the time of this writing (22).

A crucial part of the smoking cessation services was the offer of effective pharmacotherapies. The evidence shows that in any setting pharmaceutical treatment (nicotine replacement therapy and/or bupropion) approximately doubles success rates (16), (17). The chronology of policies on these medications is outlined below.

Smoking cessation pharmacotherapies

Nicotine replacement therapies (NRTs) had been licensed in England since 1982, when nicotine gum was introduced as a prescription-only medicine. Unfortunately, the Advisory Committee on Borderline Substances at the time decided that the gum was a “borderline substance” (not a truly medicinal product with clinical or therapeutic value), which meant that the gum should not be available on reimbursable NHS prescriptions. Only private prescriptions were therefore allowed (in which the patient pays the full price apart from Value Added Tax). When ‘blacklisting’ (when the Government blacklists a medicine it specifically excludes it from being prescribed on the NHS) was introduced, the nicotine gum was automatically added to it. In 1991, the gum became available in pharmacies over-the-counter (OTC). As the newer NRT products were introduced to the market they continued to be ‘blacklisted’ and although the criteria changed slightly, they were still not considered a priority for the use of limited NHS resources (23). Researchers and practitioners advocated strongly that NRT should be available on the NHS; indeed, this had been advocated for almost 20 years (24). Most of the other NRT products also became available through pharmacies.

The White Paper acknowledged the effectiveness of NRT but only allowed one week’s supply of NRT to be given

free to those smokers least able to afford it, who were attending the services. This was done through a voucher scheme, which was criticized because of the time and resources needed to implement it, but also because while it was a modest step forward, it was less than justified on clinical and cost-effectiveness grounds. It ignored the fact that most smokers do not use enough NRT and for long enough when they attempt to quit. Lobbying for proper reimbursement therefore intensified, led by ASH (23).

Bupropion is an anti-depressant that has been on the market in the United States of America for over ten years, and was discovered serendipitously to increase cessation in smokers. Thus, it is an entirely different class of drug from NRT. When it was introduced in the United Kingdom in June 2000, it was made available on NHS prescription, creating a disparity between the way two effective smoking cessation pharmacotherapies were treated. This had a disruptive effect on the treatment services. Finally, in April 2001, almost 20 years after it was first licensed for use in England, NRT was also made available on reimbursable NHS prescriptions. This is crucial for poorer smokers. Although there is a prescription charge for those who can afford it (about £6 or \$US 9.00) almost 80% of all prescriptions are free to users, usually because of their economic status. This means that, in effect, making NRT and bupropion available on NHS prescription makes it free to smokers who would otherwise have difficulty affording it.

In 1999, the 2-milligram gum was given a general sale license, meaning it also became available in non-pharmacy outlets like shops, supermarkets and petrol stations. This had been advocated by many health organizations (4), to enable cost-effective treatments to be as accessible and available as cigarettes. In May 2001, other NRT products were added to the general sale list.

In summary, in the United Kingdom there are currently two types of pharmaceutical smoking cessation treatments (and seven products) available: nicotine gum, the nicotine patch, the nicotine inhalator, nicotine nasal spray, nicotine lozenge, nicotine sub-lingual tablet, and bupropion. Some are available through three routes (NHS prescription, from a pharmacist (OTC), general sale, e.g. supermarket) but bupropion is prescription only:

- All of them are now available through the NHS on prescription.
- All NRTs are available in pharmacies, where they can be bought under the supervision of a pharmacist (OTC).

- Some NRTs are also available on general sale, which means any shop can sell them: 2-milligram and 4-milligram gum, all the patches, and the 1-milligram lozenge.

Thus since 1998 and the launch of the Government's smoking cessation services, there have been several significant policy changes regarding smoking cessation medications. While these were warmly welcomed from the tobacco control community, the piecemeal nature of their introduction created difficulties for those running the services.

Description of treatment services in England

At the time of this writing, in late 2002, every health authority in the country offers treatment to dependent smokers who want help in stopping through the National Health Service. This means that the treatment is free to all users (although partial payment can be required for the pharmacotherapies as described above). Each local service has a coordinator, whose role is that of service manager, although many of them also do some cessation counselling. Under them the coordinator has counsellors trained and paid to help smokers stop, and most services have also trained primary care nurses (and others like pharmacists) to include counselling of smokers within their wider work.

Exact service models vary according to local conditions, especially depending on population spread. However, in its official guidance on how to set up the services, the Government urged the services to base themselves on the evidence base which, *inter alia*, meant they should not offer treatments that do not work. One model, found more in cities, has a core central clinic where specialist counsellors run groups that offer behavioural support plus pharmaceutical aids, with satellite clinics also offering groups run in the community. This central service trains and supports community counsellors, often nurses, who offer smokers support usually in primary care settings. Other services offer both group support and individual (one-to-one) counselling in a variety of settings throughout their communities. A third service model offers all smokers individual counselling, by trained nurses, in their own primary care centre/general practice. This latter model is typically found in rural settings. Almost all services offer group and individual support backed up by pharmaceutical treatment – NRT and/or bupropion.

Smokers are encouraged to take advantage of the behavioural support offered. This maximizes cessation rates and means higher success rates than would be achieved if they only used pharmaceutical products. Thus, at the heart of the system is behavioural support, in groups or individual, which typically consists of support, teaching coping strategies and providing encouragement and help in the use of smoking cessation pharmacotherapies.

One of the original rationales for treatment guidelines and for the services proposed by them, was to engage the entire health care system in treating addicted smokers, by ensuring that when general practitioners raise the issue and advise smokers to stop, they can refer them to specialist treatment. In effect, the idea was to make tobacco dependence treatment like the treatment of any other condition in the NHS: primary care acts as initial point of contact and advice (it has been called the gatekeeper role) and then refers to specialist treatment when necessary. In Britain this had been true for many years for those addicted to illicit drugs and to alcohol, but nicotine addicts were excluded from such help.

A key role of the smoking cessation coordinator was therefore to promote the services to primary care staff (particularly general practitioners) and to offer training and support to these healthcare professionals. Involving general practitioners and other primary care staff in the treatment of nicotine dependence is important for two reasons. First, this advice triggers quit attempts in smokers, and although only a small percentage will stop as a result, this is an important effect since general practitioners can reach so many more smokers than could be reached through intensive support alone (25), (26), (27). Secondly, although smokers can self-refer to the services, a greater throughput will be achieved if general practitioners and other primary care staff also refer or recommend smokers to the services.

This model of care is now beginning to be achieved but a few cautionary statements are in order. First, when NRT and bupropion could be prescribed, it became easier to encourage general practitioners and other primary care staff who can prescribe, to play a greater role in intervening with smokers. Secondly, most attention focused initially on specialist support. This was because recruiting and training the specialist staff had to take precedence, but also because of the way the monitoring and evaluation were set up, such that only those smokers who set a quit date and received specialist support counted towards the



targets. Thus, there still remains work to be done in fully engaging general practitioners and their staff.

Finally, tobacco dependence treatment has not yet been truly “normalized” within the system. This is because the system of funding the NHS is being changed, with control being devolved to a more local level – to primary care groups (serving a population of around 200 000). This means that from April 2003 onwards, primary care groups will take over the funding and running of these services, and the Government’s mechanism for encouraging them to do so is the setting of targets – cessation targets for example. It remains to be seen, therefore, how fully, or in what form these services survive. The Government initiative has certainly raised the profile of tobacco dependence treatment hugely, but not in itself normalized it.

Success of the treatment services

The Government insisted on the services monitoring their throughput and outcome from the beginning and has published bulletins periodically. From April 2001 to March 2002, the third year of the services, 220 000 smokers came to the services and set a date for stopping smoking (the base for all outcome statistics). Of these 120 000 said they had stopped smoking four weeks later, an increase from 65 000 the previous year (22). During the second year of the services going nation-wide there were around 500 new staff. Using conservative assumptions, the cost effectiveness of the new services was estimated at just over 600 per life year gained for treated smokers aged 35–44 years and 750 for those aged 45–54 years (28). These figures are consistent with estimates published with the original national guidelines (6). In addition to the collection and publication of official statistics, the Government also commissioned a research team to conduct a detailed evaluation of the services. This project is ongoing and will publish a series of papers reporting the impact of the services, including how well they are reaching smokers, especially low-income and pregnant smokers. Although the data are not yet available the Government intends that they will be published in full, in a scientific journal, and presented at the 12th World Conference on Tobacco or Health, in Helsinki, in August 2003.

Discussion

To what extent can this English/United Kingdom experience be reproduced in other countries? It grew within a tradition of relatively well-funded addictions research and

health education. It also had the active support of the campaigning organization ASH and the medical professions over more than 30 years. Successive Governments accepted, at least in principle, the desirability of combating tobacco (and of raising revenue from it by increasing taxes, which has been shown to increase demand for the treatment products (29)). In addition, it benefited from the existence of a national health service, with a relatively well-developed infrastructure. And of course this story took place in a wealthy country. Can any aspects of this experience be exported?

From an historical perspective the role of the medical profession was critical. The Royal College of Physicians (RCP) (which created ASH) and later the British Medical Association campaigned vigorously over decades and provided crucial health and scientific information. The series of RCP reports was extremely influential. The national treatment guidelines published by the HEA in 1998 were not only evidence based, but were also formally endorsed by more than 20 professional organizations, especially medical and nursing bodies. Getting this endorsement took time and money but almost certainly enhanced the authority and influence of the resulting document.

The United Kingdom story also depended on the fusion of several strands at a crucial time (a new Government promising action against tobacco) and on some of the personalities involved. Obviously, the personalities cannot be reproduced, nor can the Government, but at a crucial time there were key people outside and inside the Government who were knowledgeable about tobacco addiction, who were committed to taking things forward, and who learned to work together. It seems unlikely that things can move forward without enough committed individuals – one of their key roles being to present the case to Government.

The effectiveness and cost effectiveness evidence was critical and influenced the Government to act. This can be reproduced elsewhere if committed individuals and organizations persist in making the case, backed up by good data. Treating dependent smokers is one of the most cost-effective interventions that a health service can deliver, which means that if health care systems offer such services, they will eventually release resources (no longer needed to treat lung cancer for example) for other uses. In spite of this, when the United Kingdom Government was developing plans for the treatment services, their Finance Ministry insisted on careful estimates of how much the services would cost. So another key point is that tobacco

dependence treatment services are relatively cheap (they do not, for example, require enormously expensive high-tech equipment).

Although not all countries will be able to afford all the elements described here, the research does not need doing again everywhere, and much of the expertise is exportable. There are several countries now implementing treatment for tobacco dependence, and thus there are more and more people capable of helping (including with training).

Lessons learned

- *Present the evidence and arguments until they are accepted.* The English experience suggests this can be done. Since funding will always be an issue, the effectiveness and cost-effectiveness evidence and arguments are crucial. In England, smoking costs the health service about £1,500 million each year. The smoking treatment services are costing approximately £25 million a year. Funding smoking cessation interventions will have a knock-on effect and reduce other health-care expenditure. The anomalous position of nicotine addiction compared with the provision of treatment for other addictions might also be highlighted.
- *Obtain necessary government commitment to develop a treatment system nationally.* In England this took many years. However, it need not take so long in other countries since much of the evidence and arguments are available from other countries' experience. For example, WHO's Europe Partnership Project in partnership with the British Government, *The case for commissioning smoking cessation services (18)*, could be adapted by other countries.
- *Work with doctors at as high a level as possible and benefit from their influence.* The voice and involvement of the medical profession was crucial in Britain, so the lesson to smoking cessation specialists and campaigners is work with doctors at as high a level as possible and benefit from their influence. If they first need educating then do that first.
- *Work together and share the load.* This includes researchers, campaigners, health professionals and government officials. This may sound obvious but it doesn't always happen. No one organization or group can do everything. In England a number of mistakes were made that could have been avoided with more sharing of expertise and foresight.
- *Learn from experience and do it even better.* In England a number of problems that could have been avoided slowed progress:
 - Set standards for and plan training, increasing capacity if necessary. There were no national standards governing training and no control over its quality or quantity, yet a huge training capacity was a predictable requirement of the project.
 - Standardize the provision of pharmaceutical treatments and make them as widely available/accessible as possible. This also means make them affordable. When the project started, neither NRT nor bupropion was available on NHS prescriptions. Their introduction on prescription, as well as being made more widely available over the counter and through general sale, was done in a piecemeal way; again the need for widely available pharmaceutical aids was totally predictable.
 - Give the new services time to become well established. An enterprise as huge as this takes time to develop, but the short-term funding promised caused recruitment difficulties and staff losses. We suggest that whatever initiative or level of funding a country proposes to develop treatment for tobacco dependence it should have at least five years guaranteed development to promote stability and commitment from its staff.
 - Whereas targets for numbers of smokers quitting through the smoking cessation services can be helpful, care needs to be taken that this does not create a tension between throughput and reaching priority groups. In England, the key priority group was the more deprived smoker who may be more dependent and therefore more in need of help.
- *Make appropriate investments.* Up to £50 million was announced by the Government for educational programmes and up to £60 million for treatment systems. There has been some debate as to whether this balance of investment is the right one. It is important that a significant investment be made in developing smoking cessation services, but it is vitally important to maintain the wider tobacco control strategy with appropriate investment made in other areas, such as mass media campaigns. Certainly countries that do not yet have population approaches to motivating smokers to stop will probably not want to start by developing treatment services.



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