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Passive smoking: history repeats itself

Strong public health action is long overdue

See pp 968, 973, 980

In 1962 and 1964 the Royal College of Physicians in London and the surgeon general of the United States released landmark reports documenting the causal relation between smoking and lung cancer.[1 2] During the next quarter century, extensive research confirmed that smoking affects virtually every organ system. By 1990, the surgeon general concluded that "smoking represents the most extensively documented cause of disease ever investigated in the history of biomedical research."[3]

The history of research on passive smoking followed a parallel course. The 1982 surgeon general's report on smoking and cancer reviewed the first three epidemiological studies published on the relation between passive smoking and lung cancer. Each showed an increased risk of lung cancer in non-smoking women whose husbands smoked. But because the evidence was not yet abundant, the report's conclusions were cautious.[4]

In 1986 the surgeon general devoted an entire report to the topic of involuntary (passive) smoking.[5] It reviewed 13 "spousal studies" on passive smoking and lung cancer, 11 of which showed a positive association. The surgeon general was now able to conclude that "involuntary smoking is a cause of disease, including lung cancer, in healthy non-smokers." Also in 1986, four other reports from authoritative bodies in the United States, Britain, France, and Australia came to similar conclusions.[6-9]

The next watershed was publication of a comprehensive report on environmental tobacco smoke by the US Environmental Protection Agency in January 1993.[10] By that time, 30 epidemiological studies on passive smoking and lung cancer had been published from eight countries, 24 of which showed a positive association. The Environmental Protection Agency classified environmental tobacco smoke as a known human carcinogen, to which it attributed 3000 lung cancer deaths annually in American non-smokers. The agency also documented causal associations between exposure to environmental tobacco smoke and lower respiratory tract infections such as pneumonia and bronchitis, middle ear disease, and exacerbations of asthma in children.

The agency calculated extremely low probabilities that the epidemiological findings had occurred by chance: a one in 10 000 probability that 24 of 30 studies would show a positive association between passive smoking and lung cancer; a one in 10 million probability that 17 out of 17 studies characterised by exposure level would show an increased risk at the highest exposure level; and a one in a billion probability that 14 out of 14 studies would show positive dose-response trends.[11]

An equally impressive report on environmental tobacco smoke was published last month by the California Environmental Protection Agency.[12] That report, like its federal counterpart, was the subject of extensive peer review, expert committee review, public comment, and revision. It affirmed the findings of the US Environmental Protection Agency on the link between environmental tobacco smoke and lung cancer and respiratory illness. It also concluded that passive smoking is a cause of heart disease mortality, acute and chronic heart disease morbidity, retardation of fetal growth, sudden infant death syndrome, nasal sinus cancer, and induction of asthma in children.

Two important studies from the Wolfson Institute of Preventive Medicine in London, published in this week's *BMJ*, comprise the latest chapter in the history of passive smoking research. Hackshaw et al (p 980) conducted a meta-analysis of the epidemiological studies on passive smoking and lung cancer, which have now reached 37 in number.[13] After careful adjustment for bias and dietary confounding, they determined that marriage to a smoker increased the risk of lung cancer by 26% (95% confidence interval 8% to 49%), a conclusion bolstered by strong evidence of a dose-response relation and by linear extrapolation of risk in smokers.

Law et al (p 973) conducted a meta-analysis of 19 epidemiological studies of environmental tobacco smoke and ischaemic heart disease.[14] After adjusting for dietary confounding, they determined that environmental tobacco smoke caused a 23% increase in risk of ischaemic heart disease (95% confidence interval 14% to 33%). They found confirmatory evidence from studies of active smoking, which showed a substantial effect on risk of ischaemic heart disease at low dose. The authors reviewed human and animal studies of exposure to environmental tobacco smoke in relation to arterial atheromatous disease, platelet aggregation, and infarct size after experimental occlusion of a coronary artery, which help to explain the biological plausibility of a low dose effect of environmental tobacco smoke on the risk of ischaemic heart disease.

The systematic reviews from the Wolfson Institute,[13 14] the California Environmental Protection Agency,[12] and the US Environmental Protection Agency,[10] and the five reports released in 1986[5-9] make it

clear that exposure to environmental tobacco smoke is a cause of lung cancer, heart disease, and other serious illnesses. In the United States alone, it is responsible each year for 3000 deaths from lung cancer, 35 000 to 62 000 deaths from ischaemic heart disease, 150 000 to 300 000 cases of bronchitis or pneumonia in infants and children aged 18 months and younger (causing 136 to 212 deaths), 8000 to 26 000 new cases of asthma, exacerbation of asthma in 400 000 to 1 million children, 700 000 to 1.6 million visits to physician offices for middle ear infection, 9700 to 18 600 cases of low birth weight, and 1900 to 2700 sudden infant deaths.[12] Those figures make passive smoking one of the leading preventable causes of premature death in the United States.[15]

History repeats itself not only in research on active and passive smoking, but in the actions of the tobacco industry to deny and obfuscate the findings of that research. The latest example, which compares the hazards of second-hand smoke with the "risks" of drinking milk and eating biscuits,[16] is as inane as were the industry's denials of the hazards of active smoking in past decades. Their public pronouncements are particularly cynical in the light of contradictory statements in their internal documents,[17] and their recent settlement (for $300 m) of the class action lawsuit in Florida on behalf of flight attendants harmed by second-hand smoke (p 968).

Public health action to eliminate exposure to environmental tobacco smoke is long overdue. The minimum acceptable standard for indoor facilities is to allow smoking only in physically separated and separately ventilated areas.[18 19] A total ban on smoking is preferred on three grounds: it provides maximum protection of non-smokers, it avoids exposing smokers to extremely high levels of environmental tobacco smoke in designated smoking areas,[20] and it avoids the costs of constructing separately ventilated smoking areas. Health advocates should pursue all strategies that would help accomplish that goal, including education, legislation, regulation, and litigation.

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High cost, low volume care: the case of haemophilia

Reverting to central funding might be the only option

Haemophilia is a rare and expensive condition. In Britain it affects 5418 males with factor VII deficiency and 1109 with factor IX deficiency, and in 1994 they used 158 million units of factor VIII and 9 million of factor IX at an average cost of 30p per unit. Over the past 20 years the amount of clotting factor used per patient has increased, and both the quality of the clotting factors and methods of administration have improved.

In theory the nature and level of treatment is specified in contracts between purchasers and providers, but at our centre, which cares for 14% of the haemophilic population of England and Wales, contract revenue is regularly outweighed by the cost of care. Our cost pressures are similar to those of any high cost, low volume clinical service in any general trust. Accumulating experience suggests that the present funding arrangements are failing; the danger is that such services will become a liability and be eliminated by both providers and purchasers.

Clotting factor concentrate represents 50-80% of the total direct cost of haemophilia care.[1] Over the past

15 years the use of concentrate in Britain has risen threefold. For reasons of viral safety recombinant factor VIII is the treatment of choice[2]; recombinant factor IX is also likely to become so once it is licensed. However, while intermediate purity plasma derived clotting factor costs 32p per unit and is exempt from value added tax, recombinant factor VIII costs 52p per unit and is liable to 17.5% VAT. Thus in our centre, where the median annual use of concentrate for an adult is 72 000 units, the annual cost per patient would be £23 000 for intermediate purity plasma derived concentrate but £44 000 (including VAT) for recombinant factor VIII.

A further cost pressure has been changes in treatment strategy, particularly the introduction of prophylaxis for children. Traditionally a patient with severe haemophilia received clotting factor concentrate (30 IU/kg) after a bleed and could expect 30-35 bleeds per year.[3] Long term prophylactic regimens, introduced before any sign of joint damage, have benefited patients by preventing joint damage and improving the quality of life.[4] These regimens, however, require a fourfold increase in clotting factor use. Although in Britain the number of boys aged under 10 with severe haemophilia is small (only 385 in 1994), for our trust the cost of giving 31 of them prophylaxis with recombinant concentrate is about £2m. Furthermore, contracts for this care have to be negotiated with 16 health authorities. Perhaps the greatest difficulty, however, is the unpredictability of individual clotting factor requirements. For example, the concentrate required for a total knee replacement for haemophilic arthropathy could double the annual cost of treatment for a single patient.

Although information on the cost effectiveness of prophylaxis is beginning to emerge,[5] there is no hard information on the benefits of using recombinant factors over plasma derived concentrate. Currently we rely on the biological plausibility that recombinant factors are likely to prove beneficial in the long term. Whether it is economically desirable to increase spending on patients now is open to argument, but within the constraints of an annual contracting round adopting a longer perspective is clearly difficult. Should we be investing in alternative ways of reducing costs, such as gene therapy and continuous infusion? What are the costs and benefits of liver transplantation, which can cure haemophilia?[6]

Additional costs of iatrogenic infections

Iatrogenic problems add to the cost pressures. In 1979-86, 1321 individuals with haemophilia in Britain were infected with HIV from clotting factor concentrate, and 560 are currently alive. Our centre looks after 70 of them. All concentrates are now sterilised and no new transmissions have occurred since 1986.[7] Such processes have added considerably to the cost of treatment, but there is good evidence that monoclonally purified products slow the deterioration of the immune system in HIV positive patients.[8] Although additional funding was provided to pay for placing patients on these high purity products, patients with end stage AIDS consume upwards of 50% more clotting factor than when they are asymptomatic.[9] It has been estimated that 25 years from seroconversion—that is, around the year 2008 for the haemophilic community—20% will still remain AIDS free.[10] With the advent of triple antiviral therapy, the cost of drug treatment as well as a longer duration of life will add to the costs of caring for these patients.

Most patients treated with large pool clotting factor concentrates between 1965 and 1985 were infected with hepatitis C virus. A fifth are coinfected with HIV, which accelerates the progression of the liver disease.[11] Many are treated with interferon, calculated at a lifetime cost of £70 555-£195 407.[12] In addition, since coagulation factors are synthesised in the liver, increased amounts of factors VII, VIII, and IX are required when the liver fails. These deaths are largely unpredictable but occur at a rate of two a year in our centre. There is no additional funding for concentrate in these circumstances.

Contracting for this high cost service is made harder by the uneven geographical spread of patients. In 1994, 42 of 85 haemophilia centres treated fewer than 10 patients with severe disease; only three centres, including our own, treated more than 110. These three centres treated over half the 2368 patients needing clotting factor concentrates in 1994 in England and Wales.

These escalating and unpredictable costs mean that expenditure on haemophilia treatment is often not covered within a block contract. As a result the trust and purchasers find it increasingly difficult to ensure that patients with haemophilia receive appropriate care while sustaining the level of service in other specialities. In the long term it may be necessary to revert to central funding for this rare, expensive, unpredictable, and lifelong condition and others like it.

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Formula fever: allocating resources in the NHS

Simple formulas weighted for standardised mortality ratios may still work best

A new set of weighted capitation formulas are being used for allocating resources to health service "purchasers." Since the 1970s the NHS has used formulas to promote a more equitable allocation of resources for hospital and community care. The Resource Allocation Working Party (RAWP) recommended that cash should be distributed on the basis of the size and age-sex distribution of an area's population, taking into account relative health care needs as indicated by its standardised mortality ratio.[1] This highlighted the fact that the regions in the south of England were receiving more than their fair share of resources and initiated a gradual redistribution to the poorer and sicker north.

In the 1980s regression analysis was used to estimate the influence of health and socioeconomic factors on health care use.[2] Recent research at York University used more statistically appropriate techniques which also adjust better for the effect of variations in supply and consider resource use rather than just bed days. The resulting indices of need for acute[3] and psychiatric[4] health services are more sensitive to the influence of socioeconomic factors and, had they been implemented, would have redistributed resources from richer to poorer districts. However, the previous government decided to allocate only around 75% of the funds using these needs weights. Most of the community health services budget was excluded on the pretext that the research was based on hospital episodes: community health service data are not routinely recorded. The decision not to weight the community health services budget according to need contradicted the epidemiological evidence.[5] The effect was to dampen the redistributive effects of the York formulas, resulting in losses for poorer districts.[6]

The then Secretary of State was pressured into commissioning research on weighting community health needs. In this issue of the *BMJ* Buckingham and colleagues report the results of part of this research (p 994).[7] Along with other research on the use of community health services,[8] and a refinement of the market forces factor which takes into account geographical differences in the cost of providing care, this research is now used to allocate resources to health authorities.[9]

The methods used are necessarily cruder because of the general lack of good data and the dependence on a few providers for records of community health contacts. The results are particularly important, however, for two reasons. Firstly, they confirm that the government was indeed wrong to exclude community health services from needs weighting for the past two years. For many of the individual programmes and for all the community services aggregated, the correlation between the prediction of the new formulas and the York indices is over 80%.[8] Secondly, the results again show the importance of the standardised mortality ratio. This measure summarises the cumulative social and health experience of people living in an area and is a sensitive indicator of general health care needs[10] and powerful predictor of community health care use. Its advantage over other variables which are derived from the census is that it is available routinely on a regular basis and is not manipulable.

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The empirical work over the past years seems to have validated the original idea of the Resource Allocation Working Party to use a measure of the death rate as an indicator of relative need.[1] There are no unique and valid indicators of health care need, and, no matter how sophisticated the analysis, research based on the use of services tends to underestimate the effect of poverty because the middle classes are better at accessing health services. Because of this, a similar result could be produced by basing a formula simply on population size and age, weighted by the under 75 year standardised mortality ratio.[11] This would be simpler and more transparent than combining the results of 10 different but highly correlated instruments.[9]

We have become besotted with the production of ever more refined empirically based formulas. The marginal increase in NHS equity resulting from these compared with formulas based on standardised mortality ratios is probably very small. Formula fever has distracted attention from the now more important issue of how the allocated resources are spent. Health authorities and general practitioners should focus their attention on whether current spending patterns reinforce socially produced inequalities[12] and, if so, doing something about this at local level.[13]

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Ethics and international research

Research standards are the same throughout the world; medical care is not

A recent commentary in the *New England Journal of Medicine* by Lurie and Wolfe criticised placebo controlled trials designed to identify simple and effective interventions to prevent maternal-infant HIV transmission in developing countries.[1] Their commentary reflects a lack of understanding of the realities of health care in developing countries and ethical principles of research. The commentary and an accompanying editorial by Angell[2] take a position that would prevent developed countries from collaborating with developing countries to identify practical and affordable health interventions.

Lurie and Wolfe propose that studies supported by the United States government should provide all participants with the same level of care that is available to Americans. This is a misinterpretation of the Council for International Organisation of Medical Sciences guidelines, which call for universal principles of ethical research, not universal standards of medical care.[3] Under the guidelines, interventions must be appropriate for the country where the research is conducted and no research subjects may be denied care that would otherwise be available for them. The studies criticised adhere to these principles.

Also, providing care routinely provided to women and their infants in America, at a cost of thousands of dollars per patient, would serve as a powerful incentive to participate in trials in countries where per capita health care expenditures are usually less than $10. This would violate the guideline to avoid undue inducements for participation in research and would make almost all research sponsored by US organisations in these countries totally impracticable. If these unsustainable services were provided on a temporary basis what would happen when the research project ended and local practitioners could no longer provide diagnostic tests, infant monitoring, and intensive care units necessary to support the regimen?

In 1994 the ACTG 076 study conducted in the United States and France showed that a complex regimen of zidovudine administered orally from mid-pregnancy to delivery, intravenously during labour, and orally to the infant for six weeks reduced the rate of maternal-infant HIV transmission from 25.5% to 8.3%.[4] This regimen has become the standard in America and some European countries but in most developing countries has not been implemented because the medical care infrastructure cannot identify HIV infected women early in pregnancy or deliver the regimen; most women seek prenatal care too late in pregnancy to be offered a regimen that begins early in the second trimester; many deliveries take place outside hospitals; intravenous infusions for all women are impractical (or unsafe); and the regimen costs 100-500 times the healthcare funds available per person per year in many countries. Moreover, many pregnant women are anaemic and anaemia is a common complication of zidovudine therapy, so the safety of the 076 regimen is unknown in these settings.

Studies are in progress to evaluate short course zidovudine regimens that would be more affordable and practical than the 076 regimen. Since the effectiveness of these short regimens is not known, they are being compared with placebo. In these countries zidovudine and other antiretroviral drugs are not available for pregnant women. Women taking part in these studies are fully informed of their HIV infection status, the purpose of the study, the probability of receiving drug or placebo, and the possibility of not participating. The studies have been reviewed by ethics committees locally and at major universities and discussed by the National Institutes of Health, the Centers for Disease Control and Prevention, and the World Health Organisation. Also, data and safety monitoring boards monitor the studies. None of the participants are being denied the care they would otherwise have. Any analogy with the Tuskeegee study, where none of these safeguards were in place, is offensive.[5]

Lurie and Wolfe argue that all women in these studies should receive some zidovudine. They propose comparing a short course regimen to the 076 regimen or comparing two different short course regimens. Both designs would probably yield uninterpretable results. If the 076 regimen was shown to be better than the short course no one would benefit as the 076 regimen could not be implemented and we would not know if the short course was efficacious in the absence of a control arm. Until we know that short course regimens are safe and efficacious, any study showing similar rates of transmission with two different short regimens would be uninterpretable, as it would be impossible to determine the benefit produced by either regimen. Exposing people to the potential risks of research that is unlikely to answer the study question is unethical. If a short course regimen is shown to be safe and effective in future then it will become the comparison arm for future studies instead of a placebo.

Imposing the American standard of medical care on all participants in international trials funded by the United States would prevent developed nations from collaborating with developing countries to identify feasible and affordable means of preventing and treating many diseases. Not only is this considered "medical and ethical imperialism" by colleagues in developing countries; it would also have prevented the development of many interventions, such as oral rehydration, micronutrient supplementation, and low cost surgical procedures,[6-8] that have dramatically improved health care throughout the world.

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Hastening slowly: Mr Dobson plays a waiting game

A task that cannot wait is to lower expectations in the short run

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Britain's new government is at present engaged in a curious policy striptease, with more tease than strip. Hardly a day passes without the unveiling of some new initiative or the announcement of yet another working party to review specific aspects of the NHS. But we are still left waiting for the promised series of green and white papers translating the government's general aspirations into specific proposals for the NHS and public health. In this respect, the speech by Frank Dobson, the Secretary of State for Health, at the recent Labour party conference proved unrevealing.[1] There was a dribble of specifics. But the government's overall strategy remains veiled. Nor is this surprising.

Ministers face a dilemma. The frustrating reality of a financially constrained NHS struggling to cope with competing expectations has somehow to be reconciled with the rhetoric of transformation that swept ministers into office. In these circumstances the best that can be hoped for is incremental change, which, over the years, will move the NHS in the desired direction. The last thing the NHS needs is policy drama, and perhaps the most welcome aspect of Mr Dobson's speech was his emphasis on experimenting with change and testing out what works best.

The conflict between aspirations and reality is already apparent. The NHS Executive's guidance to health authorities and trusts on priorities for 1998-9[2] makes it clear that dealing with emergency admissions may make it impossible to achieve shorter waiting times. Indeed, the waiting list issue may prove as much of an incubus for the Labour administration as it did for its Conservative predecessor. Perhaps Mr Dobson should have started by asking the royal colleges to develop national criteria, on the New Zealand model, for classifying those on waiting lists by their degree of urgency. For, in the absence of such national criteria, it is impossible to know what degree of priority should be attached to devoting resources to reducing waiting lists and whether local variations in waiting times reflect variations in the local propensity to put patients on the list or genuine differences in the capacity to meet need.

The general direction of change is also becoming apparent. The new government will be able to "end" the internal market because, to a large extent, it is already dead on its feet. The substitution of long term agreements for annual contracts between purchasers and providers, the switch of emphasis from competition to cooperation, represents the endorsement of a trend that has been evident for some time.[3] There remains the problem of fundholding. Here government strategy seems to be to edge it towards voluntary euthanasia. On the one hand, fundholders will be encouraged to take part in experiments in local commissioning, so giving them a voice in the way resources are used (although it remains unclear how strong a voice it will be without control over money). On the other hand, fundholding budgets are likely to be more stringent.

Even if fundholding is gradually marginalised, however, this may not allow the government to achieve its major aim of reducing bureaucratic costs. Fundholding is expensive to administer. But locality commissioning also imposes administrative costs and it is not self evident that it will generate any compensatory efficiency gains. In any case, cutting bureaucracy is not a magic formula for giving infinite elasticity to the NHS's budget; at best it can produce one off savings and provide some temporary relief.

Long term relief will depend on decisions about total funding for the NHS. But here too ministers face tough choices. The £300 million announced earlier this week (p 971) and the £1.2 billion promised for the next financial year are designed to avert unfavourable headlines rather than promote a more effective service. For the future the government needs to develop a coherent strategy for using any extra funds that become available, as distinct from using them for fire fighting. If morale is to be raised, should priority be given to increasing the pay of NHS staff or to relieving the pressure on them by employing more staff? Answering such questions will take time. And perhaps the most urgent task ministers have is to lower expectations about what they can sensibly be expected to deliver in the short run.

Much of what they have done is welcome: for example, the abolition of gagging clauses in contracts. Other initiatives, such as the introduction of health action zones, represent interesting experiments, although past attempts to promote collaboration across administrative boundaries suggest the need for scepticism.[4] Inevitably, action has not matched rhetoric. Nor, in the time available, could it. But the new rhetoric—with its emphasis on promoting public health and on addressing inequalities—is itself important. It provides the benchmarks for assessing the government's performance over the next five years.

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