Voluntary agreement on tobacco advertising

EDITOR,—Richard Doll and colleagues report that half of all regular cigarette smokers will be killed by their habit.¹ Cigarette smoking among 11-15 year olds in England, however, is not falling,² and the government's target in the *Health of the Nation* to reduce smoking among 11-15 year olds by a third by 1994 is unlikely to be met. Tobacco advertising influences the uptake of smoking among young people,³ yet the government is against a ban on such advertising, saying that voluntary agreements provide effective control.

In October 1993 all 84 newsagents in the Metropolitan Borough of Solihull were visited to monitor the extent of tobacco advertising and the compliance of the advertisements with the voluntary agreement.⁴ Tobacco advertisements were carried on the exterior of 70 of the 84 newsagents, with a median of three items per newsagent (range 0-29). Twenty eight advertisements suspected of breaching the voluntary agreement were reported to the monitoring body, the Committee for Monitoring Agreements on Tobacco Advertising and Sponsorship. The reply from the committee confirmed that 10 items (all from Imperial Tobacco) breached the voluntary agreement as they did not include health warnings. A further seven items did not carry a health warning, but as they predated 1983 this did not represent a breach as long as the tobacco companies rectified the situation (this highlights a loophole in the voluntary agreement). Five other items had their health warning covered by other material, which thus constituted an "inadvertent" breach (that is, one for which the tobacco company was not responsible). The above items were found at 20 of the 84 newsagents.

In the committee's annual report for 1994 the Solihull survey contributed 28 of the 36 complaints, 10 of the 11 acknowledged breaches, and 5 of the 6 inadvertent breaches.⁵ These findings are similar to those in previous years, when the reporting of suspected breaches to the committee and the identification of confirmed breaches has been attributed to a small number of organisations.⁶

Our survey in Solihull confirms previous findings that breaches of the voluntary agreement are common but monitoring is generally non-existent.⁶ The voluntary agreement does not provide effective control of tobacco advertising; this removes the government's defence in its refusal to ban tobacco advertising.

Details of tobacco advertisements on exteriors of newsagents in Borough of Solihull suspected of breaching voluntary agreement and conclusion from Committee for Monitoring Agreements on Tobacco Advertising and Sponsorship regarding these advertisements

Nature of complaint	Response from committee	Details of advertising material
20 Items: no health warning	10 Breaches: no health warnings present 7 Items: no health warnings but as they dated from before 1983 they were not defined as breaches 1 Item: had health warning 2 Items: insufficient evidence to reach decision	7 Door signs indicating shop open/closed (Embassy* (6), John Player* (1)) 2 Door stickers (Embassy, *John Player*) 1 Showcase (Embassy*) 2 Window friezes (John Player*) 1 Window sticker (Golden Virginia*) 2 Exterior hanging signs (Embassy, *John Player*) 2 Door signs indicating shop open/closed (Dunhill, † Rothman†)
1 Item: health warning not 10% of area	No breach: health warning: covering correct area	
7 Items: health warnings were covered	5 Items: confirmed as inadvertent breaches 2 Items: insufficient evidence to reach decision	Showcases (Embassy* (2), Benson and Hedges‡ (2), Dunhill†)

*Manufactured by Imperial Tobacco. †Manufactured by Rothmans International. ‡Manufactured by Gallaher.

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Molecular cancer epidemiology can predict risk

EDITOR,—The pioneering epidemiological studies by Richard Doll and colleagues on the links between cigarette smoking and a wide variety of cancers provide the strongest evidence for a link between environmental exposure and induction of cancer.¹ It has come to our notice that the range of cancers induced by cigarette smoking could have been predicted by use of the new research techniques of molecular cancer epidemiology. This studies the molecular changes in people as a result of exposure to carcinogens. It also offers the opportunity of identifying aetiological agents that could ultimately lead to the prevention of cancer.

One method used in molecular cancer epidemiology is postlabelling with phosphorus-32, a technique in which DNA obtained from organs or

tissues in the body is analysed for DNA adducts, the interaction products of chemical carcinogens with DNA. The technique is extremely sensitive, allowing one DNA adduct to be detected in 10⁹-10¹⁰ nucleotides—that is, one adduct per genome. Cigarette smoke gives a very characteristic pattern of DNA adducts, which probably represents the many different adducts formed from the numerous carcinogens identified in cigarette smoke.

We have used this technique of postlabelling with ³²P to study DNA adducts from a variety of organs in the body. In the case of the lung, the major target tissue of cigarette smoke, we have reported a linear relation between the number of cigarettes smoked daily and the number of DNA adducts obtained.² A clear statistical difference between adduct levels in the lungs of smokers and non-smokers has also been found.³ Other organs and tissues that showed evidence of DNA adducts induced by cigarette smoke are the bladder, pancreas, stomach, mouth, larynx, lymphocytes, and cervix, all organs suspected of being susceptible to cancer induced by cigarette smoke.^{3,4} In contrast, no adducts induced by cigarette smoke were detected in either the liver or the breast, sites that seem not to be susceptible to cancer induced by smoking. Thus the molecular damage seems to predict the risk of cancer. Interestingly, damage to DNA may also predict coronary heart disease, since the levels of DNA adducts in the heart are higher than those in any other organ analysed to date.

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Advice to authors

We prefer short letters that relate to a recently published article and we are unlikely to publish letters longer than 400 words and containing over five references. Letters may be shortened. Your letters should be typed with double spacing and include a word count. All authors need to sign the letter and provide one current appointment and address. We encourage you to declare any conflict of interest. Please enclose a stamped addressed envelope if you require an acknowledgment.

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Evaluation of palliative care

Recruitment figures may be low

EDITOR,—In response to the paper by Ian R McWhinney and colleagues¹ we wish to report our experience of recruitment into trials in the palliative care setting. The trials were not of a palliative care service but of palliative therapeutic interventions in a specialist cancer hospital. These included randomised studies of pharmacological and non-pharmacological strategies in the management of bowel obstruction, hypercalcaemia, nausea induced by opiates, anorexia, pain, and dyspnoea as well as non-randomised studies in patients in pain.

In the 12 months to October 1994, 344 patients were referred to one of two research sisters in palliative care as being suitable for entry to one of the above studies. Both inpatients and outpatients were referred by medical and nursing staff throughout the hospital. Of the 344 patients, 109 were not approached as they did not fulfil the criteria for inclusion in the studies. Thus after full discussion regarding the implications of entering the trial 235 patients were asked if they would agree to participate in one of the studies. Only 142 patients gave informed consent. The remainder were not entered into the studies because they were too unwell or their condition had deteriorated (27), they were eligible but declined to consent (38), they lived too far away from the hospital (16), or for unknown reasons (12). Thus 41% of the patients initially referred and 60% of the patients who were approached were entered into studies. These figures are low but are likely to be higher than those achieved in other palliative care settings since the patients were recruited in a specialist cancer hospital with a high research profile, where the role of the research sister is well established.

We agree with Henry McQuay and Andrew Moore that palliative care should not be excused from conducting randomised controlled trials simply because they are difficult to do,² but our recruitment data show several of the inherent difficulties.

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- 2 McQuay H, Moore A. Need for rigorous assessment of palliative care. *BMJ* 1994;309:1315-6. (19 November.)

Patients should be randomised at time of diagnosis

EDITOR,—Ian R McWhinney and colleagues report the difficulties that they experienced in evaluating a palliative care service.¹ The underlying cause of the methodological difficulties was that patients were referred to the palliative care team late in the course of their illness.

Altogether 1268 residents of Warwickshire died between 1 July 1993 and 30 June 1994 and had a diagnosis of cancer recorded at some point on their death certificate. Record linkage showed that, before their death, 394 of these 1268 residents had been in contact with community Macmillan nurses based in Warwickshire. The first contact occurred less than four weeks before death in 159 cases and less than eight weeks before death in 241 cases.

The same problems would thus probably arise if a study similar to that attempted by McWhinney and colleagues in Canada was undertaken in Britain. It has been suggested that in an ideal future palliative care would start at the time of diagnosis and form a gradually increasing component of care between diagnosis and death.² Randomised controlled trials of palliative care should therefore recruit and randomise patients at the time of diagnosis, not during the terminal stage of illness.

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Important factors are hard to measure

EDITOR,—Ian R McWhinney and colleagues and Henry McQuay and Andrew Moore draw our attention to the problems in assessing palliative care, but their contributions also show the physical emphasis that preoccupies doctors, naturally enough, in the care of dying patients.^{1,2} Of course control of symptoms must be audited and multi-centre trials will help neutralise the overoptimistic prognosis routinely given by our profession. But what is not yet achievable, except in certain specific aspects of palliative care, and especially while the measurement of quality of life is still so crude, is any randomised trial of the fundamental problems of dying patients—loneliness and fear—and, for relatives, lack of commitment or of confidence. These require affection, understanding, and ungrudging availability as well as competence. These are so much more difficult to measure than the speed of throughput or equivalent data that are irrelevant yet close to the heart of NHS purchasers.

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Patients must be told that treatment will be randomised

EDITOR,—Henry McQuay and Andrew Moore refer to equipoise being the requirement for an ethically sound randomised controlled trial.¹ Although equipoise is a necessary condition, it is not sufficient. In addition, those whose participation is sought in a randomised controlled trial should be informed about all relevant features of that trial, an important one of which is the randomisation process. For an ethically sound trial of the sort reported by Ian R McWhinney and colleagues² it would be necessary to recruit only those patients who were genuinely ambivalent (or were prepared, knowingly, to forgo their choice) about whether to receive palliative care support immediately¹ or after a delay of one month. Although the figure is not explicitly stated in the

report, it seems unlikely that fewer than 20 of the 166 eligible patients refused to participate in the trial on this basis.

The moral and practical difficulties of informed consent in medical research frequently hinge on disclosure of the fact of randomisation. When the interventions being compared are identical in form (such as active and placebo drugs presented as indistinguishable tablets) genuine ambivalence is much more likely.

When dissimilar treatments—for instance, surgery and radiotherapy—are being compared many people will have an innate preference based on personal considerations rather than scientific evidence. In such circumstances there may be genuine clinical equipoise but the right of autonomous choice should not be removed by failure to disclose the fact of randomisation.

While many individual interventions in palliative care may feasibly be subject to randomised controlled trials, the assessment of a whole service by such means seems a tall order indeed.

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Randomised controlled trials and health services research

EDITOR,—Randomised controlled trials are viewed as the gold standard for medical research, and are advocated as an appropriate method for evaluating almost any medical intervention. However, they are neither universally applicable¹ nor, as Ian R McWhinney and colleagues show,² always realistically possible. Although they have been advocated as appropriate for use in health services research, serious problems can arise in practice that affect whether the data can be generalised.

Evaluation of programmes is a case in point. The simple act of defining the intervention to be tested can be problematic. During the development phase of a randomised controlled trial of a hospital at home scheme in Northamptonshire lengthy discussions took place between the providers, the clinicians, and the research team about the package of care to be evaluated. Agreement was finally reached, but not until the views of the provider unit, professional groups, the acute unit, general practitioners, secondary care clinicians, the primary health care team, the family health services authority, social services, the hospital pharmacy, the ambulance service, carers, the health authority, and the local research ethics committee had been taken into account. At every stage of the trial's development the views of each of these groups had to be considered. Although these problems can be resolved, the resources put into this process must not be underestimated.

Methodological problems are less easily resolved because of the lack of published material on the application of randomised controlled trials in health services research. This problem will continue with increasing use of subjective assessments of health as outcome measures in such research.³ In many instances the data on which to base calculations of sample size for these measures do not exist, and their clinical relevance has yet to be determined.

It is unfashionable to publish results of unsuccessful studies. We urge, however, that research that highlights the difficulties in this area should be given space in journals. This would help to ensure that impractical projects were not funded and that