and overheating babies; the campaign started in 1985-6, before advice about avoiding the prone sleeping position was available.² Since 1991 the emphasis of this campaign has been maintained, while we have tried to ensure that as few babies as possible sleep prone. We have advised that the normal maximum indoor clothing needs at 18°C are a nappy, vest, sleepsuit, and cardigan, with coverings of a sheet and three single blankets. Before the Department of Health's publicity, virtually all babies in this district who died had been placed and were found dead in the prone position.

The table shows the cumulative effect of these two campaigns in reducing postneonatal infant mortality. By 1991 the sudden infant death syndrome due to avoidable overheating had become rare, but detailed investigations at the scene of death showed that many babies were still hot or sweating when found dead; this has been postulated as likely to happen if feverish babies sleep prone.^{3,4} Since 1992 no cot deaths have occurred in this district.

Postneonatal infant mortality in Scarborough district, 1983-94

Years	No of births	All deaths	All cases of SIDS	Cases of SIDS due to avoidable overheating
1983-6	6061	39	30	19
1987-91	8124	20	16	5
1992-4	4519	5	0	0

SIDS=Sudden infant death syndrome.

Significance of reduction in all cases of the sudden infant death syndrome: 1983-6 v 1987-91, $P=0.003$; 1987-91 v 1992-4, $P=0.007$ (two tailed χ^2 test for independence with Yates's continuity correction).

All districts will continue to have sporadic cases of the sudden infant death syndrome, as unexplained deaths occur at every age. The Department of Health's advice is empirical, so that success in following the advice cannot prevent all cases of the syndrome and failure to follow the advice cannot be used as the explanation. The fall in unexpected deaths suggests, however, that the few that now occur are likely to be explicable and avoidable, even before the challenge of preventing parental smoking is addressed. The target rate for the syndrome in future years should be zero, not just a downward trend.

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Infant respiratory death rates mirror sudden infant deaths

EDITOR,—E A Gilman and colleagues speculate about the reasons for the dramatic falls in sudden infant deaths that occurred during the first and second quarters of 1992 as compared with the decreasing trends in the rates for these two quarters over the previous four years.¹ The dramatic falls occurred after the launch of the campaign to encourage parents to put infants to sleep on their backs and to avoid smoking near them or overheating them.

The authors put forward as one possible explanation of these falls the interaction between the prone sleeping position and the underlying patho-

genic mechanisms that it affects. In this regard, we would draw attention to the fact that the secular and seasonal trends in the monthly numbers of sudden infant deaths over recent years have been mirrored by those for infant deaths attributable to respiratory disease. The figure shows the two series for the years 1986-92. The concordance between

Numbers of sudden infant deaths and infant deaths attributable to respiratory disease, England and Wales, 1986-92 (source: Office of Population Censuses and Surveys)

these two series is evident in the summer troughs as well as the winter peaks. This phenomenon suggests that whatever has led to the seasonal variation and decreasing trend in sudden infant deaths, including the pronounced decrease during 1992, has produced a similar pattern for infant deaths attributable to respiratory disease. Furthermore, we have shown that during 1986-90 there was a close association between the monthly incidence of respiratory infectious diseases in the age group 0-4 years.²

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Dutch doctor convicted of murdering disabled infant

EDITOR,—Tony Sheldon reports the death at the hands of a Dutch gynaecologist of a baby with serious congenital malformations who was in great pain and had a limited life expectancy; the doctor was convicted of murder but not sentenced.¹ Bringing about the death of a severely disabled infant is an attempt to wipe out a distressing problem for the attendant adults by attributing their anguish to the child and then bringing that to a quick end. This overlooks three important facts.

Firstly, the natural adult reaction to any crisis of expectation is to try to deny it. Doctors can deny reality by continuing aggressive treatment for an incurable illness as well as by agreeing to bring it to a quick end. In either case this can arrest or delay the anger, guilt, bargaining, and depression of grief, which may all arise during its natural resolution but which, when thwarted, can leave bereaved people with serious emotional upsets. Removing the problem may not stop the pain.

Secondly, babies are born ready to relate to parents along all five sensory pathways. Even when serious disability hinders such normal mutual interaction (and this is not always so) parents who attempt it are more likely to feel satisfied that the child's life, though brief, was enhanced by their

personal care. Their grief is also likely to resolve better.

Thirdly, babies who are born disabled do not know that this is their condition and may never do so. They may cry because of discomfort, but symptomatic relief is available for them, just as it is for adults. Those who advocate "mercy" killing for babies (and others) tend to polarise their options into futile attempts to cure or final advice to kill. There is, however, a third way. The specialty of palliative medicine is inadequately represented in the Netherlands but is well established in Britain, both for adults and for older children. Dying babies, too, can be helped to live until they die.

All these points were illustrated in a paper that a colleague and I wrote in 1988.² To ignore the normal reaction to grief and to destroy the opportunity for parents and the child to have even a brief time to enjoy each other is to sow a legacy of chronic emotional pain. For most of us, disabled babies included, life's chief value lies not in the number of days or in physical and mental assets but in secure and creative relationships. Any doctor-parent-baby relationship should have this as its goal.

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Misleading meta-analysis

Public policy is based on results of epidemiological meta-analyses that contradict common sense

EDITOR,—Matthias Egger and George Davey Smith's scepticism about the validity of meta-analyses whose conclusions are contradicted by those of single megatrials¹ can be extended to meta-analyses of epidemiological studies whose findings contradict biological common sense. The alleged causative contribution of passive smoking to lung cancer is based, among other things, on a meta-analysis of 10 case-control studies and three prospective studies that showed a highly significant 35% increased risk among non-smokers living with smokers compared with non-smokers living with non-smokers.² This risk is especially pronounced for adenocarcinoma in the periphery of the lung (a histological category not associated with smoking in Doll and Hill's studies of doctors) rather than for the central squamous cell cancers seen most commonly in active smokers.³ If the conclusion of this meta-analysis is to be believed it is necessary to suppose that carcinogenic cigarette smoke inhaled in massive doses over 30 years causes one type of lung cancer whereas the same cigarette smoke at much lower doses causes a completely different type of cancer, not usually associated with smoking, in a different part of the lung.

Similarly, on the basis of a meta-analysis of 78 trials of a reduction in salt intake in hypertension it has been claimed that a reduction of 3 g a day in Western populations could reduce the incidence of stroke by 26% and of ischaemic heart disease by 15%.⁴ This seems improbable for two reasons. Firstly, the immediate physiological response to salt reduction is that salt is conserved in the kidneys. Secondly, the maintenance of a steady blood pressure is under the control of at least six independent physiological homeostatic mechanisms, so the contribution of salt intake, if any, is likely to be very small. The results of salt restriction have been more plausibly attributed to a placebo effect.⁵

The alleged roles of passive smoking in causing lung cancer and excess salt in causing hypertension have been endorsed by many medical bodies, incorporated into public policy, and presented to the public as scientific facts that should be acted on. It is a revealing commentary on the intellectual status of public health epidemiology that the statistical fiction on which this and similar misleading advice is derived should have gone unchallenged for so long.

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Registers for clinical trials already exist

EDITOR,—In their editorial on misleading meta-analyses, Matthias Egger and George Davey Smith point out that bias is a major cause of error because of the tendency for negative trials to disappear from view.¹ They call for registers of clinical trials to be established. The Medical Research Council already runs a register for cancer trials, and the national research and development programme has a project register system, which can do the job for other trials.

Ethics committees should ensure that investigators intend to publish their trial, perhaps requiring all patients to be informed that registration and publication will occur so that they can be reassured that their participation will benefit others. The project register system can then register the trials so that even the smallest negative trial, which is most likely to be the subject of publication bias, will be available to meta-analysis of the future.

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Variability among studies should be investigated

EDITOR,—Matthias Egger and George Davey Smith explain how pooling of smaller studies can turn out to be misleading after the subsequent publication of larger trials and suggest that meta-analyses of small trials should now be distrusted, even if their combined effect reaches significance.¹ Yet they also point out that evidence from mega-trials will continue to be unavailable for most medical interventions, and hence meta-analyses of smaller trials remain the only apparent way of appraising available evidence.

The various statistical manoeuvres that the authors suggest to remedy this situation ignore one important focus of meta-analysis—namely, the degree of variability, or spread, among different studies. One way of analysing this is to perform a χ^2 test of deviations of individual studies from the overall mean achieved by pooling the studies.² A significant P value for this test suggests a considerable amount of variability around the summary result. This approach could provide a more precise statistical test of whether meta-analysis of results of small trials should be distrusted or questioned.

Interestingly, the next issue of the *BMJ* con-

tained a meta-analysis of the efficacy of tricyclic drugs in treating child and adolescent depression in which a χ^2 test of heterogeneity of the different studies' results (as measured by changes in outcome score) was performed; this was significant at $P=0.05$.² This significant variability across studies was largely ignored in that paper. This, alongside the neglect of measures of dispersion in Egger and Davey Smith's editorial, testifies to a current tendency to overlook the issue of variability across results of studies in meta-analysis.

Obviously if all studies give the same result there is no point in a meta-analysis; such a statistical exploration becomes of interest only in the context of variability among studies. But widely differing findings across many studies surely demand an exploration of the reason for the variability, not just an attempt to derive a mean result. In the case of drug trials in particular, in which significant heterogeneity in results may be accounted for by different drug doses used, accounting for variation may be a better purpose for meta-analysis than merely deriving an average result.

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Fish oils and cardiovascular disease

EDITOR,—In their editorial B N C Pritchard and colleagues concluded that fish oils have beneficial effects on lipids and the haemostatic system, but they pressed for more studies in diseases related to atherosclerosis.¹ We wish to reinforce this recommendation, particularly in relation to diabetes.

Two studies in which we have been involved have suggested possible adverse effects on the coagulation system. In the case of patients with insulin dependent diabetes a randomised trial showed significant increases in fibrinogen and clotting factor X concentrations in the group that took a fish oil supplement.² In a separate trial in patients with non-insulin dependent diabetes factor VII concentration increased significantly in the group receiving the fish oil preparation; this group also showed worsening glycaemic control.³ Fibrinogen and factor VII may be risk factors for ischaemic heart disease.⁴ Thus these apparently adverse effects on the coagulation system may outweigh other potentially beneficial effects on platelet function. We are therefore concerned that the use of fish oil in diabetic subjects should be reserved for those participating in well designed trials to investigate further the effect of fish oils on the risk of ischaemic heart disease.

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Advance directives

Approved guidelines are now required

EDITOR,—While it is useful to know that the Law Commission has followed the House of Lords in appearing to support the concept of advance directives,^{1,2} it is disappointing that more formal guidelines have not been suggested or approved. Keeping concepts in loose terms may satisfy the lawyers, who may in turn make incomes out of the loopholes, but this will not help our patients. Who will define capacity and the ability to consent or withhold consent? At present the final arbiter is the law, but recent cases suggest that this is muddled and not helpful to medical practitioners or patients.

We like to believe that adults without mental illness have a right to self determination, yet Re T and Re S both indicate that this is not so.^{3,4} Re T concerned a Jehovah's Witness who refused blood transfusion: the courts decided that her decision had been made and her religious persuasion determined under coercion and rejected her autonomous choice not to be given a transfusion when she could not defend herself against that decision.³ Re S concerned a woman whom the court ordered to have a caesarean section against her will.⁴ In contrast, in another recent case, Re C, a patient with paranoid schizophrenia in hospital, who thought that he was a medical practitioner, refused treatment and was deemed competent by the court to so do.⁵

If competent people refuse treatment in the present then the ability of an advance directive to be binding in the future must be severely compromised. In addition, if an incarcerated psychotic patient can be granted full competence on medical matters then presumably demented or other equally compromised patients will be able to make full autonomous decisions, upheld by the courts, irrespective of any existing directive. The only thing that will be achieved will be further legal intrusions into clinical decision making; patients do not stand to benefit.

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Law Commission's report makes no provision for dissenting doctors

EDITOR,—There is more to some advance directives than the extension of autonomy by a once competent patient. That of the Voluntary Euthanasia Society, for example, requires that insulin is withheld when required from a signatory who develops presenile dementia. If that advance directive were legally enforceable the doctor would have to give way to a patient's wish to have death brought forward by unreasonable measures.

Len Doyal¹ does not mention a serious deficiency in the Law Commission's draft legislation—namely, the lack of any provision for a doctor to dissent for medical or moral reasons from implementing an advance directive. If the document cannot require doctors to act unlawfully, as the Law Commission claims, then it should not require them to act unethically either.