health care are under threat everywhere as health care becomes a commodity and the private sector moves in.[8] Drastic environmental problems, such as the changing climate and the depletion of the ozone layer, threaten essential life supporting systems and are likely to hurt poor and marginalised people first.[9] Virulent diseases emerge and re-emerge. Action by everyone concerned with health is needed on all these fronts.

At the international level the World Health Organization could still act as a beacon of hope in turbulent times, just as it did in 1978. But its position has been weakened over the past two decades, and other organisations, most notably the World Bank, have taken the lead in formulating international health policy, sometimes with malign effects. The WHO needs to assert its principles once more. As a start it could encourage governments, non-governmental organisations, and international agencies to work towards a vision of health for all; stress the need for partnerships between health care and other sectors; and advocate the need for major investments in health, especially increases in human resource development, without which the Alma Ata declaration will remain a statement of intent.

The WHO's partnership with transnational pharmaceutical companies needs to be re-examined, as the inclusion of industry representatives on critical policy committees— especially the drug pricing, vaccine production, health care costing, and selection of the essential drugs list—is rightly viewed with suspicion. The WHO must be an open and democratic organisation that can also respond to the grass roots: listening to the people should not be difficult for Gro Harlem Brundtland, a former politician, and it is regrettable that she is not attending the People's Health Assembly. Her success as director general depends on the growth of popular health movements all over the globe which will be able to back up her call to make health central to the development process.[10]

As a result of the assembly, we hope to see the formulation of advocacy agendas at local, national, and international levels, as well as an increase in the sharing of knowledge and experience between people committed to the principles of primary health care. Above all we feel it is critical that the assembly assembles broad-based networks for change which can implement the vision of Alma Ata more effectively. We hope that the Assembly will prove to be a significant step towards revitalising the powerful vision of "Health for All" and we encourage everyone who shares our fears and aims to join us.

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Economic evaluation and clinical trials: size matters

The need for greater power in cost analyses poses an ethical dilemma

General practice pp 1383, 1389

Randomised trials of health care interventions are increasingly attempting to tackle issues of cost effectiveness as well as clinical effectiveness. A good example of this appears in the two papers describing the clinical[1] and economic evaluation[2] of psychological therapies in primary care in this issue of the *BMJ* (pp 1383,1389). The use of clinical trials as a vehicle for prospective cost effectiveness analysis presents challenges for successful evaluation, and the methods of conducting trial based economic evaluation are still in their infancy.

Several commentators have emphasised that health economists should be involved from the outset in the design of trials that seek to report on cost effectiveness,[3] rather than being asked to add in the economic variables as an adjunct to the main trial (in a so called "piggyback" arrangement).[4] The reason for this is because design considerations are different for clinical and economic analyses.

The tendency of resource use variables to follow a skewed distribution[5] means that cost variables generally have higher variance than clinical outcomes. Furthermore, the fact that most new interventions involve resource shifting such that increased resource use in one area is offset by resource saving elsewhere makes the net cost of introducing such interventions unclear. Finally, many different categories of resource use may be involved, each with different unit cost weights and each showing varying degrees of difference between trial arms. Typically, therefore, comparisons of treatment cost will require greater sample sizes than the corresponding clinical comparison. If the goal of the study is to show that the resulting cost effectiveness ratio is significantly below some upper

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limit on the maximum society is willing to pay for health gain, then it is even more likely that the sample size requirements for economic evaluation will be many times those required to show a clinical effect.[6]

The consequence is that piggyback economic evaluations will typically be underpowered for both the cost analysis and any cost effectiveness analysis, even if the main clinical comparison is appropriately powered. The dangers of underpowering studies are well documented in the clinical literature,[7] and this has led to the recommendation to use estimation rather than hypothesis testing when reporting results of clinical evaluations.[8] Exactly the same principle should be used in economic evaluation. The evaluative technique of cost minimisation analysis is often used unthinkingly to select the least costly intervention when no statistically significant difference in health outcome is detected. Yet this use of cost minimisation is built on the sandy foundations of hypothesis testing and the mistaken assumption that "absence of evidence is evidence of absence."[9] Similarly, it is inappropriate, given the likely low power to detect cost differences in a piggyback study, to interpret a statistically significant difference in clinical effect and an insignificant cost difference as evidence of cost effectiveness.

For these reasons, and in common with the recommendation for clinical evaluation, the focus of cost effectiveness studies should be on estimating cost effectiveness, even when either cost or effect differences lack conventional statistical significance. Low powered studies will be revealed in the wide confidence limits around results, and readers will not be misled.

In this issue Bower et al report that their study was designed as a cost effectiveness analysis.[2] However, they later report that there was no power calculation for costs, with the sample size for the study being determined by the main clinical outcome. Not surprisingly, therefore, it found no significant differences in cost between the treatments either at 4 or 12 months' follow up. As the authors emphasise, we must be careful in interpreting these results.

Health service decision makers will probably be most interested in the fact that, though there is no evidence of any long term treatment effect, the cost difference is not inconsistent with an additional cost to society of £458 for cognitive behaviour therapy or £952 for non-directive counselling, at conventional levels of significance. The authors chose not to present cost effectiveness results directly, although it is clear that any such estimate based on the data from this trial would have high variance.

Ideally, of course, studies that attempt to address economic questions should be powered on the economic variables. But then they would almost certainly be overpowered with respect to the clinical outcomes. Would this be a problem? Some might argue that the ethical basis of randomisation would be questionable and that it would be inappropriate to continue a trial beyond the point at which clinical superiority has been determined beyond reasonable doubt. Given current ethical committee guidance and the consent forms that patients sign on entering a clinical trial this is no doubt true. However, inquiry into the cost effectiveness of treatment interventions is a legitimate enterprise. Failure to recruit enough patients to give unequivocal treatment and policy recommendations could be seen as unethical, leading to delay in providing cost effective treatments, delay in curtailing cost ineffective treatments, and a consequent underachievement of potential health gain from available resources within the NHS.

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The failings of NICE

Time to start work on version 2

Despite the protestations of its boss, the National Institute for Clinical Excellence (NICE) is an instrument for rationing health care.[1,2] Unfortunately, it's not a very good one. A government with spine would learn from the failings of NICE and move on to version 2. Perhaps this is a job for after the next election, whoever wins.

NICE, which covers only England and Wales, began in 1999 with three main functions.[1,3–5] Firstly, it appraises new technologies, including drugs, and decides which should be encouraged in the NHS and which should be held back. Its other functions are to produce or approve guidelines and to encourage quality improvement. The biggest push for NICE came from political disapproval of "postcode prescribing:" patients on opposite sides of the same street may receive or be denied treatment because they fall under different health authorities, each with different policies on which treatments they will fund.

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