1 Reid S, Wessely T, Crayford T, Hotopf M. Medically unexplained symptoms in frequent attenders of secondary health care: retrospective cohort study. *BMJ* 2001;322;767-9.
2 Fink P, Sorensen L, Engberg M, Holm M, Munk-Jorgensen P. Somatization in Primary Care: Prevalence, Health Care Utilization, and General Practice Recognition. *Psychosomatics* 1999;40:330-8.
3 Hartz AJ, Noyes R, Bentler SE, Damiano PC, Willard JC, Momany ET. Unexplained Symptoms in Primary Care: Perspectives of Doctors and Patients. *Gen Hosp Psychiatry* 2000;22:144-52.
4 Kessler D, Lloyd K, Lewis G, Gray DP. Cross sectional study of symptom attribution and recognition of depression and anxiety in primary care. *BMJ* 1999;318:436-40.
5 Kennedy BL, Schwab JJ. Utilization of Medical Specialists by Anxiety Disorder Patients. *Psychosomatics* 1997;38:109-12.
6 Simon GE, VonKorff M, Piccinelli M, Fullerton C, Ormel J. An international study of the relation between somatic symptoms and depression. *N Engl J Med* 1999;341:1329-35.
7 Simon GE, Goldberg D, Tiemens BG, Ustun TB. Outcomes of recognized and unrecognized depression in an international primary care study. *Gen Hosp Psychiatry* 1999;21:97-105.
8 Bass C, Bond A, Gill D, Sharpe M. Frequent attenders without organic disease in a gastroenterology clinic: patient characteristics and health care use. *Gen Hosp Psychiatry* 1999;21:30-8.
9 Smith GR. The course of somatization and its effects on utilization of health care resources. *Psychosomatics* 1994;35:263-7.
10 American Psychiatric Association. *Diagnostic and statistical manual of mental disorders*. 4th ed. Washington, DC: American Psychiatric Association, 1994.
11 Pilowsky I. *Abnormal illness behaviour*, Chichester: John Wiley, 1997: 39-41.
12 Salmon P, Peters S, Stanley I. Patients' perceptions of medical explanations for somatisation disorders: qualitative analysis. *BMJ* 1999; 318:372-6.

Managing depression in primary care

The type of treatment matters less than ensuring it is done properly and followed up

Several recent studies have evaluated alternative approaches to managing depression in primary care. The range of disease and the treatments examined have varied widely, no doubt contributing to the variation in results. Nevertheless, randomised trials leave little doubt that antidepressant drugs are efficacious in major depression,[1 2] and recent evidence suggests efficacy in dysthymia and subsyndromal depression as well.[3] But what role does counselling play in the primary care management of patients with various forms of depression? Recent trials in primary care have produced conflicting results and conclusions.

The paper in this issue by Chilvers et al (p 772)[4] and an earlier report from the same study[5] address three important questions about treating major depression in primary care. Is there a difference in the effectiveness of drugs versus counselling? Is the non-standardised counselling provided by most mental health providers effective? Does matching treatment with patient preferences increase effectiveness? In Chilvers et al's study only the first question is addressed using a randomised design. Unfortunately, small sample sizes and difficulties in follow up urge caution in interpreting the results. Regarding the second and third questions, we must settle for non-experimental comparisons within this sample and with previous reports.

Chilvers et al conclude that generic counselling appears to be as effective as antidepressant drugs for major depression, though patients given drugs may recover more quickly. There may be differences in longer term effects as well. Tables 3 and 4 in the paper show that patients randomised to drugs were 16% more likely to have a "good" global outcome, 10% more likely to ever remit, and 30% less likely to be depressed by research diagnostic criteria. These differences in 12 month outcomes, none of which reached statistical significance, raise a conundrum. Are the differences between drugs and counselling in the randomised group large enough to have implications for practice?

Randomised controlled trials on both sides of the Atlantic now provide evidence that different approaches to counselling—cognitive-behavioural,[6] interpersonal,[1] and problem solving[2]— have equivalent efficacy to drugs in treating major depression. But in these studies the "talking therapy" is applied by protocol using specially trained counsellors who are often monitored for adherence to the protocol. Chilvers et al's study placed few constraints on either the drug treatment or the type of counselling other than that the counselling should be provided by an experienced mental health professional in six sessions. In effect therefore they compared non-standardised antidepressant use with non-standardised counselling by experienced mental health professionals in general practice. Because statistical tests showed no significant differences in effectiveness the authors conclude that generic counselling is effective. Recent comparisons of more rigorously applied non-directive and cognitive-behavioural counselling with usual general practitioner care among a broader range of depressed patients found both specific therapies to be better than usual care at four months but not at 12.[7] This may suggest advantages for more specific, standardised counselling over more generic approaches. Only direct comparisons of generic counselling with more standardised, specific approaches will resolve this question.

Primary care p 772

As to the implications for practice, the results in the patient preference group may be relevant. Over two thirds of the patients refused randomisation because they preferred a particular form of treatment, and nearly two thirds of them preferred counselling. Both the high proportion of people with a preference and the high proportion of them preferring counselling are consistent with other recent findings.[7 8] Within the patient preference group there were no differences in outcomes between the groups treated with counselling or drugs. Thus, regardless of one's interpretation of the randomised results, patient selected counselling or drugs appear to be equally effective if the counselling is provided by an experienced therapist.

It remains possible that patients without preferences will have better long term outcomes with drugs under real world circumstances where follow up may be sporadic. The major differences between usual care and protocol driven care for depression are the assurance of adequate intensity of treatment, whether counselling or drugs, and the consistency of follow up.[9 10] The low rates of assessment at 12 months in this study illustrate the difficulties with follow up in everyday practice. When care is organised to assure intensity and

BMJ 2001;322:746–7

continuity of treatment, then the totality of evidence strongly indicates no difference between specific counselling or drugs. Giving patients with major depression their choice of treatment and then assuring adequate intensity of treatment and follow up represent high quality care.

Edward H Wagner *director, McColl Institute for Healthcare Innovation*
Gregory E Simon *investigator*

Center for Health Studies, Group Health Cooperative, 1730 Minor Avenue, Suite 1300, Seattle, WA 98101, USA

GES has received research funds from Pfizer and Eli Lilly, EHW from Parke-Davies.

1 Schulberg HC, Block MR, Madonia MJ, Scott CP, Rodriguez E, Imber SD, et al. Treating major depression in primary care practice. Eight-month clinical outcomes. *Arch Gen Psychiatry* 1996;52:913-9.
2 Mynors-Wallis LM, Gath DH, Day A, Baker F. Randomised controlled trial of problem solving treatment, antidepressant medication, and combined treatment for major depression in primary care. *BMJ* 2000;320:26-30.
3 Williams JW, Barrett J, Oxman T, Frank E, Katon W, Sullivan M, et al. Treatment of dysthymia and minor depression in primary care: A randomized controlled trial in older adults. *JAMA* 2000;284:1519-26.
4 Chilvers C, Dewey M, Fielding K, Gretton V, Miller P, Palmer B, et al. Antidepressant drugs and generic counselling for treatment of major depression in primary care: randomised trial with patient preference arms. *BMJ* 2001;322:772-5.
5 Bide N, Chilvers C, Churchill R, Dewey M, Duggan C, Fielding K, et al. Assessing effectiveness of treatment of depression in primary care. Partially randomised preference trial. *Br J Psychiatry* 2000;177:312-8.
6 Scott C, Tacchi MJ, Jones R, Scott J. Acute and one-year outcome of a randomised controlled trial of brief cognitive therapy for major depressive disorder in primary care. *Br J Psychiatry* 1997;171:131-4.
7 Ward E, King M, Lloyd M, Bower P, Sibbald B, Farrelly S, et al. Randomised controlled trial of non-directive counselling, cognitive-behavior therapy, and usual general practitioner care for patients with depression. I: Clinical effectiveness. *BMJ* 2000;321:1383-8.
8 Dwight-Johnson M, Shervourne CD, Liao D, Wells KB. Treatment preferences among depressed primary care patients. *J Gen Intern Med* 2000;15:527-34.
9 Peveler R, George C, Kinmonth AL, Campbell M, Thompson C. Effect of antidepressant drug counselling and information leaflets on adherence to drug treatment in primary care: randomised controlled trial. *BMJ* 1999;319:311.
10 Simon GE, Von Korff M, Rutter C, Wagner E. Randomised trial of monitoring, feedback, and management of care by telephone to improve treatment of depression in primary care. *BMJ* 2000;320:526-7.

Beyond Helsinki: a vision for global health ethics

Improving ethical behaviour depends on strengthening capacity

The fifth revision of the 1964 Declaration of Helsinki, published in October 2000, sets out international standards for conducting medical research with human subjects.[1] Revisions of this or any other research ethics code are unlikely to make research more ethical throughout the world, however, without some means of strengthening capacity to promote and implement such standards.

Strengthened capacity in research ethics is needed in both developed and developing countries, though the need is particularly acute in developing countries. A recent *Washington Post* investigation into research in developing countries revealed "a booming, poorly regulated testing system that is dominated by private interests and that far too often betrays its promises to patients and consumers."[2]

Research in developing countries was a flash point of the fifth revision of Helsinki because the declaration retains the requirement that new treatments should be tested against the "best current" treatment. Critics argue that this standard does not allow the testing of low cost, sustainable treatments, such as aspirin for coronary artery disease, which might yield substantial health improvements in developing countries but are inferior to the best current treatment in developed countries. Bloom has argued convincingly that global health would be better served by adopting a standard of the "highest attainable,"[3] and we have offered an expanded concept of the standard of care in research, advocating that visiting researchers need a deeper understanding of the social, economic, and political context of trials in developing countries.[4]

But even another revision of Helsinki that incorporated these recommendations would not, in isolation, improve the ethics of research in developing countries. Rather, people are the key—to apply international codes to local circumstances, develop and enforce national codes, staff research ethics boards, and implement research ethics processes.

The Fogarty International Center of the US National Institutes of Health is spearheading the movement to strengthen capacity in research ethics by committing $5.6m (£3.7m) over four years to train faculty from developing countries in bioethics. These North-South partnerships will be further strengthened by South-South regional networks (such as the Forum for Ethical Review Committees in Asia and the Western Pacific) and global networks, such as the Global Forum for Bioethics in Research, which brings together researchers in developing countries and organisations that support clinical research.[5]

The crucial step, yet to be taken, is to strengthen ethics centres and training programmes in developing countries. Direct support by international donors will be essential, at least initially. A model is the International Clinical Epidemiology Network (INCLEN), a programme initially supported by the Rockefeller Foundation that created a network of clinical epidemiology units around the world: we are proposing an INCLEN for ethics. With 30 training centres each producing 12 trainees a year, for example, 3600 people would be trained over 10 years to chair research ethics boards and teach research ethics to investigators, research ethics board members, students, and policy makers. The total cost would be about $100m.

Important questions remain about how to sustain this vision; the career paths of the trainees; selecting the centres; how communities, non-governmental organisations, and international organisations could be involved; and how to evaluate the effort. Moreover, how would this effort integrate with a broader vision of public health, and the process of strengthening national health—and health research—systems?

BMJ 2001;322:747–8