- Specialist teams could get together and plan some well focused clinical trials to provide the evidence on which to base improved clinical guidelines.
- Those who fund clinical research should take a proactive position and encourage proposals for these trials.
- The licensed indications for albumin (and crucially the summary of product characteristics on which manufacturers base their documents[7]) must surely be given a thorough and prompt overhaul as it appears that these are divorced from both clinical opinion and the conclusions of the systematic review.

Meanwhile—for the next six years or so—if I have the misfortune to be seriously sick, I hope I can choose my doctor, take the fluid he or she decides on, and worry about all the other hazards of being in hospital.[13]

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Flushing away the fat

Weight loss during trials of orlistat was significant, but over half was due to diet

Obesity (body mass index >30 kg/m^2) is a serious disease which predisposes to heart disease, hypertension, stroke, diabetes, osteoathritis, obstructive sleep apnoea, gallstones, and some cancers sensitive to sex hormones. It accounts for 2-7% of total healthcare costs and a substantial proportion of disability pensions. Obesity is out of control in most affluent countries of the world, and its prevalence is increasing rapidly in developing countries. The World Health Organisation describes it as a global epidemic.[1] This week, with the launch of orlistat, hopes have been raised that there is a new, effective weapon against the rising prevalence of obesity.

In 1976 in the United Kingdom an expert committee sounded a warning that obesity was "one of the most important medical and public health problems of our time."[2] In 1980 a survey showed that 6% of men and 8% of women were obese,[3] and in 1992 the government set a target that the prevalence of obesity (then 8% of men and 12% of women) should be reduced back to the 1980 levels by the year 2005.[4] Despite these brave words the prevalence continues to increase: the latest data show that 13% of men and 16% of women are obese.

The excitement about a potential new drug treatment for obesity is not new: at the beginning of this decade there were high hopes for the efficacy of fenfluramine. The largest multicentre trial enrolled patients who were initially about 36 kg overweight and who were randomised to either diet and fenfluramine 15 mg twice a day or diet and placebo. After 12 months the dropout rate of the drug group and the placebo group was 37% and 45% respectively and the weight loss among completers 9.82 kg and 7.15 kg.[5] However, enthusiasm for centrally acting appetite suppressants was waning even before the recent cardiovascular side effects were reported: the annual number of prescriptions dispensed in the community in England fell steadily from 384 000 in 1991 to only 81 000 in 1997.

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Orlistat, which last month was licensed for prescription in the UK and the rest of the European Community, is a powerful inhibitor of pancreatic lipase, so some 30% of dietary fat is not digested but is excreted in faeces. In a two year double blind multicentre trial 743 obese patients (average weight 100 kg) were prescribed a diet in which 30% of the energy was from fat and which provided 600 kcal/day less than calculated expenditure.[6] The 688 patients (93%) who were compliant during a four week run in period on this diet and placebo capsules, during which they lost about 2 kg, were then randomised to either 120 mg orlistat three times daily or placebo for 12 months, during which the orlistat group lost 10.3 kg compared with 6.1 kg in the placebo group. As usual, almost all of this loss occurred in the first six months. At the end of the year patients were randomly reassigned to orlistat or placebo and a weight maintenance diet. At the end of the second year those continuing on orlistat had regained about 2 kg, while those switched to placebo had regained 4.6 kg. The drop out rate was low.

Many patients taking orlistat experienced fatty stools, increased defaecation, and oily spotting (so the test was not completely double blind), and after two years on orlistat up to 5.8% of them had abnormally low blood concentrations of β carotene, vitamin D, or vitamin E.

It is too early to know the contribution which this new drug will make to the control of obesity. The weight losses achieved are statistically and clinically significant, but the diet accounts for more than half of

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the loss. If we assume that the average extra weight loss of 23 g/day in the first six months on orlistat is entirely explained by fat malabsorption then about 17 g/day of fat was lost in the faeces which would normally have been absorbed: this would reduce the amount of energy available from the diet by 156 kcal/day. Similar rates of weight loss would have been achieved over six months if energy intake had been reduced by a similar amount: this is not impossible with well supervised outpatient dieting.[7] Furthermore, some of the weight loss in patients taking orlistat is probably explained by patients reducing their fat intake to avoid the adverse effects of steatorrhoea. When intestinal bypass operations were introduced for the treatment of obesity they caused massive weight loss, but this was explained by reduced food intake, not by faecal energy loss.[8]

Journalists (but not the manufacturers) have suggested that this new drug will enable fat people to eat what they like and still lose weight. This is highly misleading. Anyone taking orlistat who eats a high fat diet will receive a powerful incentive to reduce fat intake. It will be ironic if this new drug succeeds by exactly the action which it was said not to have—by inducing obese people to keep to a low fat reducing diet.

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US managed care: has the UK anything to learn?

Fishbowl medicine is here to stay

A few years ago at an international conference the American health economist, Uwe Reinhardt, said that we were all about to enter an era of "fishbowl medicine." Clinical freedom was disappearing. Clinicians would be increasingly subject to inspection. Instead of exercising their professional judgment about appropriate treatment, they would be required to follow protocols and guidelines and they would be held accountable for their decisions, especially if they departed from those guidelines. A new book by Ray Robinson and Andrea Steiner of Southampton University suggests that Reinhardt was right—at least about the United States.[1]

Based on a report prepared for the Department of Health, the book is a systematic review of the US experience of managed care and an analysis of what lessons, if any, the United Kingdom can learn. It paints an extraordinary picture of the US situation. Managed care institutions such as health maintenance organisations or preferred provider plans now cover half of the insured population, and even conventional fee for service insurance systems are increasingly using managed care techniques. Clinicians are subject to prospective utilisation reviews and preauthorisation requirements; concurrent reviews as treatment proceeds; retrospective reviews once treatment has been completed; and sometimes even mandatory second opinions. They have to follow clinical guidelines and their performance is continuously monitored and compared with that of their peers. Fishbowl medicine has definitely arrived.

But is it a good thing, and, if so, does it point the way for the NHS? Here the picture is not so clear. Most of the studies of managed care have concentrated on an issue of great concern to the US but of less interest to the UK: the ability of managed care systems to hold down costs while maintaining quality, as compared with fee for service systems. Since the NHS is already rather successful at holding down costs, and since many US managed care organisations are moving towards NHS systems of cost control, such as capitation payment systems and primary care gatekeeping, there is little for Britain to learn here.

But Robinson and Steiner do believe there are things to be learnt from US experience about specific techniques of utilisation control. One general lesson is that the more tightly organised a managed care organisation, the greater the impact on performance—with higher screening rates, more cost consciousness, and improved (or at least maintained) quality of care. In such organisations doctors also had more consistent practice styles, including legibility of records, use of diagnostic procedures, and in the process of care. This has obvious implications for primary care groups, both for their organisational structure and, given that tightness of organisation is generally easier for smaller groups, for their optimal size. Another lesson concerns the availability of treatment choice: managed care organisations were most successful in encouraging cost consciousness when clinicians felt that they had medically reasonable options.

Finally, some specific areas of health care were more amenable than others to restrictions in use, including mental health care and chronic disease management. However, there are some doubts about the impact on quality in the case of mental health care. Although the studies reviewed on chronic diseases showed no adverse impact on quality, a four year health outcomes study published too recently to appear in the book showed worse outcomes for

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