to emphasise that "scientifically, efficacy is most convincingly established by demonstrating superiority to placebo in a placebo-controlled trial."⁸ Equivalent guidelines produced by the Food and Drug Administration are more detailed. Exceptions are respected (as, for example, in trials of antibiotics where existing treatments prolong life) but, for the most part (and treatments for depression, anxiety, pain, heart failure, and hypertension are examples), when considering the licensing of a new drug the administration clearly prefers data from clinical trials comparing the effect of the product with that of a placebo.^{10 11}

The value of placebo controlled trials to the drugs industry, consumers, clinicians, and administrators in the health service add yet further dimensions. Industry has to comply with the regulatory authorities' rulings, and in many respects it is in the company's interests to compare the new product with only a placebo. By carefully selecting the researchers, companies can use such trials to familiarise opinion formers with their new products. And, of course, at the launch of a new product the last thing a company wants is a study showing that its product is less effective than the competition. In contrast, consumers, clinicians, and administrators would be keen to discover how the efficacy of the new drug compares with established treatment.¹² For this, placebo controlled studies are unhelpful.

Confusion over the use of placebos in clinical trials needs resolving. When a new drug is being developed every effort must be made to determine whether the product is effective in the condition for which it will be used. Studies should be rigorously controlled, and in many circumstances the most reliable indication of the drug's effectiveness will come from trials directly comparing the product with a placebo. Well designed placebo controlled clinical trials will be needed for each clinical end point and, once efficacy is established

for these, research should switch to comparisons with conventional products. Manufacturers have a responsibility to ensure that data on efficacy are collected as efficiently and as quickly as possible. There is no place for a myriad of small, poorly conceived, placebo controlled studies that can offer little real advance. Drug companies, which alone have data on the trials being undertaken, are the only group that can curb such practices.

Relying on public scrutiny introduces too much delay as such duplication may not be evident for years, when the results of the various studies are eventually published. Licensing authorities should standardise and make explicit their requirements for placebo controlled studies. Finally, the blanket Helsinki recommendations, which undermine the use of placebos generally, need revision.

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Pregnancy in women with cystic fibrosis

Outcomes for mother and baby have much improved

The first successful pregnancy in a woman with cystic fibrosis was reported in 1960—at a time when the median survival of children with the disease was less than 10 years.¹ The patient died six weeks after delivery, and the authors concluded that "cystic fibrosis is seriously complicated by pregnancy." Since then reports have documented a gradual change from high fetal loss and maternal death due to cor pulmonale and respiratory failure to a good chance of a successful full term delivery of healthy infants to mothers whose overall health may be little changed.²⁻⁵ Sadly, this outcome is not available to patients whose health is poor or to those few women who have been sterilised or warned not to conceive.

How, then, in the late 1990s should doctors approach the issues of fertility, contraception, and pregnancy in their women patients with cystic fibrosis? No reliable data are available on fertility rates in these women. Puberty and the establishment of regular menstruation are often delayed, and women with severe disease may develop secondary amenorrhoea due to undernutrition.⁶

The cervical mucus is thicker in women with cystic fibrosis, but this seems not to bar conception, and reliable contraception is important for all women. In our experience oral contraceptives are the most widely used method. Sex steroids are fat soluble and so their absorption might be impaired, but pharmacokinetic studies have shown therapeutic concen-

trations after standard doses and a medium dose (30 µg oestrogen) combined pill should be the first choice.⁷ Additional barrier methods should be used during courses of oral or intravenous antibiotics as these may further reduce absorption.

One recent projection suggested that 4% of women with cystic fibrosis become pregnant each year (North American Cystic Fibrosis Foundation's national patient registry, 1992). Whenever possible, pregnancy should be planned and couples should have access to genetic counselling. The man should be offered testing to determine his carrier status. If he is a carrier chorionic villus sampling should be considered since the risks of the couple conceiving an infant with cystic fibrosis are 1 in 2 and they may wish to consider selective termination in the first trimester.

Women with severe disease have to recognise that they may be unable to complete a pregnancy, and that their premature death might leave a motherless child. Even relatively healthy women may not wish to take these risks, and counselling may be needed to help them cope with difficult decisions. Some women will choose to terminate their pregnancy, but general anaesthesia may be hazardous when lung function is impaired. Regional or spinal anaesthesia is used in some centres, but termination may also be performed medically with mifepristone and prostaglandin.^{8 9}

For women who choose to go ahead with pregnancy the assessment of risk related to the mothers' initial health is not easy. Many of the available data came from small retrospective studies, which may be out of date. Some recent British data showed that if before pregnancy a woman's forced expiratory volume in one second was less than 60% of the predicted value there was a substantial risk of premature delivery, an increased rate of caesarean section, some loss of lung function, and a risk of respiratory complications and early death of the mother.⁵ Other studies have confirmed that women with impaired lung function, decreased body weight, and complications such as cor pulmonale and diabetes mellitus have an increased risk of prematurity, fetal complications, and maternal morbidity.²⁻⁴

Transplantation offers a prospect of better health and increased longevity, and some women may see this as a second chance to have a family. Successful pregnancies have been achieved by women who have undergone heart-lung transplantation,¹⁰ but the increased risk of organ rejection during pregnancy and the exposure of the fetus to potentially teratogenic drugs have led to a consensus that pregnancy should not be attempted by women with transplants.

Doctors should remember that some women have such a powerful desire to have children that they may choose to become pregnant whatever the risks. The long term effects on the mother are unknown, and collaborative, large scale

research is needed to reassess the relations between pregnancy and the disease in the short and long term.

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Community care and general practice

General practitioners can identify need, provide information, and work with carers and managers

Community care for people with problems of old age, mental illness, learning disability, and physical disability did not begin in Britain in 1993. But a lot of noise was made about it then. What did happen that year was a fundamental change in the system of funding residential and nursing homes. The 1990 NHS and Community Care Act devolved the prime responsibility for means tested funding from the central Department of Social Security to local social services departments. The act also replaced an open-ended and rapidly expanding budget with a limited budget based on individual assessments of needs.¹

There has been much apparent change and apprehension. Yet, after the second financial year, the debate on community care seems to have gone comparatively quiet. Has anything of substance actually changed? How well is the system working? Has "monitoring fatigue" set in?² Has there really been enough money? Some local authorities have reported budgetary crises,³ but most have managed with the resources allocated to them, sometimes by tightening the criteria used to assess people's eligibility for community care. Inevitably, targeting services cost effectively has become even more important in the past year.⁴ But, generally, the reforms of community care seem to have had a smooth take off. The price for this may be the expense of replacing one system of institutional care, in hospitals, with another, in residential and nursing homes. The number of long stay beds in hospitals is probably getting close to its nadir, given the recent exhortations to health care purchasers to reconsider the availability of beds, at least for patients requiring continuing care⁵ and acute admission to psychiatric care.⁶

No wonder general practitioners are expressing confusion about what is or is not happening in community care. The BMA surveyed general practitioners recently and found that,

of the third who returned their questionnaires, almost half thought that community care services had deteriorated and just a quarter that they had improved.⁷ General practitioners said they were becoming more involved in community care. Some with central roles in monitoring, supporting, and caring for patients receiving community care are attending multi-disciplinary case conferences.

One key issue for general practitioners is whether the move from secondary to primary care is simply a way of off loading responsibilities. Responsibilities for medical care in residential and nursing homes are often poorly defined, and general practitioners may be expected to take on even more treatment, monitoring, and advocacy in these settings in future.⁸

Another potentially expanded role for general practitioners is greater support for informal carers, for whom family doctors might seem to be natural allies. But a recent project by the King's Fund, an independent health care think tank, suggested that such alliances were rare.⁹ Carers expressed needs for more information, for the identification of carers in general practices' information systems, and to be viewed as coworkers with their own needs for support. But general practitioners cannot be expected to take on much more work, and, even with special facilitators, the King's Fund's project found difficulties in changing practice. Although there is some information that only a general practitioner can impart, much can be done by other members of the primary health care and mental health teams and by social workers. Well produced pamphlets, videos, and other material for carers are available¹⁰ but are not always easy to find.

Purchasing of community care services by fundholding general practitioners is in its early days. The close contacts already established through district nurses and health visitors in primary care teams may have minimised turbulence.