should have a full urodynamic investigation before having any kind of surgical repair.

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Minerva's comment was not evidence based

EDITOR,—Minerva states that, for conservative treatment of breast cancer, tumours of over 3.5 cm and age over 70 are absolute contraindications.¹ We disagree. Four randomised clinical trials that included 3197 patients have consistently shown that breast conservation is as safe as mastectomy for breast cancers up to 4 cm and even 5 cm provided that a clear surgical margin is obtained and patients receive postoperative radiotherapy to the breast.² With regard to age, to our knowledge there are no data that prove that old age would be an independent unfavourable prognostic factor for breast saving procedures. On the contrary, local recurrence may be much lower in this age group than in younger women.³ Moreover, older women wish to retain their physical integrity as much as young patients do.⁴

It is a pity that, at a time when evidence based decision making is gaining acceptance, Minerva should uncritically mention a conclusion without a good scientific basis.

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Reservations about conservative surgery for early breast cancer are unjustified

EDITOR,—E A Benson suggests that tumours over 2 cm in size should not be treated by breast conservation surgery because they seem to be associated with an increased risk of local recurrence.¹ To support this Benson reports data from Nottingham.²

In a comprehensive review of factors affecting local recurrence after breast conservation (wide excision and quadrantectomy and postoperative radiotherapy) we have identified 28 publications that have correlated tumour size and local recurrence. In 25 there seems to be no relation between tumour size and the risk of local relapse. Even in the Nottingham study the actuarial recurrence curves for tumours less than or greater than 2 cm approach each other at eight years, which suggests that with increased follow up the difference in local recurrence rates between these two groups may not be substantiated. The message from the literature is clear: the size of a tumour is not related to the risk of local

recurrence. There is thus no scientific basis for Benson's concern about performing breast conservation surgery for tumours larger than 2 cm.

Benson is correct in pointing out that, regardless of tumour size, it is important to ensure that the margins of excision are clear. While other factors such as lymphatic and vascular invasion and tumour grade have been reported consistently to be associated with local recurrence after breast conservation, they are qualitatively less important than obtaining clear resection margins.³

Benson indicates that all patients having breast conservation surgery should have a level II or III axillary dissection. The problem with this is that the lymph nodes will be involved in less than a tenth of patients who have impalpable cancers, and to submit all these patients to a full level II or level III axillary dissection seems excessive. A less didactic and more flexible policy of managing the axilla was outlined in the ABC of Breast Diseases⁴ and reflects not only our current practice but, we believe, current best practice.

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Centres that work with cochlear implants listen to views of deaf community

EDITOR,—Rupert Gauntlett points out that a congenitally deaf child given a cochlear implant may not develop normal speech and so may not thrive in a mainstream school.¹ He also emphasises the importance of sign language and "the vibrant culture of deaf people" in allowing congenitally deaf children to acquire language and mentions the opposition of some congenitally deaf adults to implantation for children. Our editorial on cochlear implantation² was designed to draw attention to the Medical Research Council's recent report on the national cochlear implant programme in Britain.³ In the space available we had to limit our remarks to the chief findings of this report, so we were unable to cover many other important issues.

The issue of cochlear implants for congenitally deaf people has been approached cautiously in Britain. Studies quoted in our editorial, however, suggest that there is a place for early implantation in suitable children who are congenitally profoundly deaf. While such children given an implant at around the age of 2 have the best chance of developing normal language and speech, not all will do so. The question of signing needs to be considered seriously for all these children, either as an alternative to implantation or to complement the child's developing oral skills. A child in whom an implant is successful can hear only when wearing the implant's speech processor, and many families believe that their child will benefit from being "bilingual" and thus able to communicate with

both hearing peers and those who use sign language to communicate.

The Medical Research Council's report emphasises the need for work with cochlear implants to be performed in "properly founded" multidisciplinary centres. These centres are well aware of the views that have, in the past, been expressed by some members of the signing community; they are particularly keen to maintain links and continue a dialogue with this community and with the British Deaf Association, which represents many of them.

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Evidence used to formulate guidelines on managing asthma did not include costs

EDITOR,—Though we applaud the efforts that went into the project to develop evidence based guidelines for primary care management of asthma in adults, we think that the results need to be handled more carefully.¹ There is category I evidence (as defined by the guideline development group) to show that dry powder devices are more effective than metered dose inhalers.^{2 3} Both of the studies providing this evidence show significant improvements in respiratory function, although they were conducted over relatively short periods. There is also good evidence from studies in other chronic respiratory diseases that dry powder devices are significantly easier to use than metered dose inhalers.⁴

Evidence based decision making is becoming a popular concept in health care.⁵ It will be useful, however, only if the quality of the evidence is improved, appropriate systems are in place to audit the evidence, the evidence is timely, and all health care professionals have the appropriate skills to decide on using the evidence.

To help advance the debate on the care of asthma we are undertaking a one year randomised controlled trial of the cost effectiveness of different inhaler devices in a primary care setting. Our study will identify and measure various factors, such as clinical outcomes, quality of life (with the short form 36 and St. George's Hospital respiratory questionnaire), costs of care, and care processes. The fundamental question relates to the costs and effects of the health care intervention; this question is not unique to asthma or even Britain. Our trial will also answer subsidiary questions, such as how good the questionnaires about quality of life are in capturing outcomes.

If evidence based guidelines are to be cost effective then all the evidence must be considered. If guidelines exclude part of the detail—for example, considerations of costs—then they must take this into account. Thus the first part of the development group's recommendations about drug delivery devices should read: "Health care professionals advising patients should recommend a device that the patients can use and comply with effectively, and in most cases this will be a dry powder device." We do not yet have the evidence to know at what level of prescribing costs a dry powder device stops being the most cost effective treatment.

Thus while the efforts of the guideline development group are helpful in opening up the debate on evidence based decision making, they have to be handled with care. They should be the vehicle for achieving better value for money in health care.

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Evidence based general practice

Findings of study should prompt debate

EDITOR,—P Gill and colleagues' adaptation to a general practice setting¹ of a study originally designed to assess interventions in an acute hospital medical firm² encouraged me to apply their methodology to acute admissions (n=50) over four weeks in the paediatric department of a district general hospital. My finding that, by Gill and colleagues' criteria, two thirds of primary interventions in this setting were evidence based is perhaps less interesting than the flaws in their study that were highlighted by my attempt to emulate it.

Firstly, Gill and colleagues cite individual randomised controlled trials and state that they did not attempt to assess the methodological quality of the trials identified. In my study at least four diagnosis-intervention pairs could be supported or contraindicated depending on which of two conflicting randomised controlled trials one chose to quote. Differences in the date of publication were not great enough to dictate the choice; an accurate assessment of trial strength is vital in such cases. Ellis *et al*'s solution to this problem was to use overviews in addition to randomised controlled trials.²

Secondly, the treatments that fell into Gill and colleagues' category (ii)—"intervention based on convincing non-experimental evidence"—were decided by a consensus of practitioners. Because of the nature of interventions in the paediatric department that I studied, this was the criterion that I adopted. The inclusion criteria for this category were therefore vastly different from those of Ellis *et al*, whose category (ii) interventions, such as cardiopulmonary resuscitation, were those "whose face validity is so great that randomised trials were unanimously judged by the team to be both unnecessary and, if a placebo would have been involved, unethical."² The general practice study, like mine, therefore included within the authors' definition of evidence based interventions a large number of treatments that proponents of evidence based medicine would call non-evidence based.

Such studies are useful for assessing the scientific basis of treatment. When, however, randomised controlled trials are not examined for

power and a consensus of practitioners is substituted for such trials in some cases, the finding that two thirds or more of interventions are evidence based is less a cause of satisfaction than a source of debate.

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Studies using more sophisticated methods are needed

EDITOR,—P Gill and colleagues¹ to respond to the challenge posed by Ellis *et al*² to assess the extent to which evidence forms the basis of practice in settings other than acute hospitals. They comment on the challenges of identifying the evidence and express concerns about its generalisability and applicability. It is not clear from their methodology, however, whether they assessed the quality of the evidence they identified, though they comment generally on issues related to quality.

We think that several methodological issues are worth highlighting. As a result of the retrospective design of the study the authors assume that the diagnostic label recorded first in the patient's medical record was the primary reason for the patient's presentation. Is this a safe assumption? Many general practitioners have had the experience of patients expressing their main concern as they leave the consulting room. Also, the authors excluded 11 patients from their sample, for whom the "attempt to cure, alleviate, or care for the patient in respect of the primary diagnosis" was referral or investigation. Their reasons for this are not clear as these are valid interventions for which evidence of efficacy might be sought. The inclusion of follow up interventions in the sample may result in the inclusion of patients whose intervention is the result of decisions taken outside general practice.

Two points arise from the results. Firstly, the fact that 76% of the interventions were drug interventions compared with the 66% reported by Fry³ casts further doubt on the representativeness of this sample. Also, although the authors report a similar proportion of evidence based interventions to that reported by Ellis *et al*,² a higher proportion of these (50% compared with 29%) were substantiated by convincing non-experimental evidence. This may reflect the fact that the interventions used in general practice are of a "low tech" nature and were often introduced before randomised controlled trials became commonly used. It means, however, that this evidence is qualitatively different from that in Ellis *et al*'s study and calls into question the appropriateness of using this paradigm in this setting. In our view, the place of evidence based practice in primary care is an important issue and needs further investigation with more sophisticated methodologies.

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Drug treatment in general practice in Japan is evidence based

EDITOR,—P Gill and colleagues report their study of the proportion of interventions in general practice that is evidence based.¹ We performed a similar study to evaluate the basis of such interventions in Japan and found that most (81%) are evidence based.

We estimated the proportion of drug treatments given to outpatients in general practice that was based on evidence from randomised controlled trials. The design was a retrospective review of case notes of patients treated between June and December 1995. Forty nine outpatients received 53 drugs prescribed by seven residents for 63 chronic diseases; 28 patients had hypertension. The setting was a training centre for general practice in Japan. New drug treatments, changes to treatment, and the addition of drugs to treatment were classed as subjective interventions. We classified levels of evidence supporting drugs as Ellis *et al* did²: (i) evidence from randomised controlled trials, (ii) convincing non-experimental evidence, and (iii) interventions without substantial evidence.

We classified groups (i) and (ii) as the "evidence group" and group (iii) as the "non-evidence group." Each drug was evaluated by discussion with senior doctors. In discussion we used literature retrieved from Medline and personal files of the senior doctors. As a result the evidence group comprised 43 (81%) of the drug treatments. Thirty two of the 53 drugs were antihypertensive agents (calcium channel antagonists, angiotensin converting enzyme inhibitors, and α adrenergic antagonists) and oral hypoglycaemic drugs. For these drugs there are no randomised controlled trials with a true end point. These drugs were classified as belonging to group (ii) on the basis of certain guidelines. If these drugs had been classified as belonging to group (iii) the evidence group would have comprised 11 (21%) of the drug treatments.

Our finding is similar to Gill and colleagues': in about 80% of cases we select drugs for chronic diseases in general practice on the basis of evidence from randomised controlled trials and guidelines. It was a problem that this evidence was not in Japanese.

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Author's reply

EDITOR,—Joanna Chikwe and Richard Meakin and colleagues share the concerns that my colleagues and I have about the quality of randomised controlled trials. I would draw their attention to two further points. Firstly, few randomised controlled trials have been carried out in general practice. Secondly, owing to