more, one could argue that it is unethical to conduct research in a biased (that is, self selected) group if one cannot define the population to which the results should be applied. Quoting guidelines of 1996 developed in a different context is hardly constructive.

With regard to her next point, is Goodare insinuating that, simply because of the structure of husband and wife or sibling teams, their work is suspect and they should be disbanded? We are also unclear why the approach taken by the self help group invalidates the results obtained by the nurse. Furthermore, contrary to what she states, all patients were provided with contact numbers for national voluntary organisations.

Derek Lowe suggests that, in this study, patients in voluntary organisation groups fared worse. It would be inappropriate, however, to dismiss all approaches of voluntary organisations as ineffective. Space precluded comment on the patients lost to follow up. There is some evidence that psychological morbidity is higher in those who fail to attend, and therefore psychological morbidity in the control group may have been even higher and the effect of the nurse even greater.

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Reply from dissenting author

EDITOR,—As a former chairman of the voluntary organisation Tak Tent, which provided support in June M C McArdle and colleagues' study, and as an author of the paper, I wish to respond to the comments with a different perspective from that of my coauthors.

I share the concern expressed by Claire Foster in her commentary on our paper¹ and by Heather Goodare about the lack of informed consent. It was argued in the study that such consent would introduce bias. Yet, as Goodare says, "women...communicate with each other" as members of an informal community of fellow sufferers who compare their experiences. I believe that the absence of informed consent produced a bias against those interventions that were not expected. Whereas the specialist nurse was a fully integrated member of the clinical team from the preoperative stage onwards, Tak Tent was unfamiliar and it was often three to five weeks after discharge before contact could be initiated owing to late referral.

Patients need to make sense of what is happening to them. What hidden messages were picked up by those assigned to Tak Tent? (Perhaps "Does someone doubt my capacity to cope?" or "Is my prognosis poor?") Perhaps the difference in the anxiety scores even at one month is explained by the stressful effect of such uncertainty. Unfortunately, the study lacks information about the individual perceptions of the subjects. Nick Black has recently written about the limitations of randomised trials that ignore all context.²

Successful counselling requires the willing participation of the client. In practice only a minority of patients seek such help; therefore it is not surprising that 50 patients refused Tak Tent's support. The study took no account of compliance; it simply applied intention to treat analysis. Also, a client's contact with Tak Tent's counselling service normally lasted weeks rather than months. In retrospect, Tak Tent's decision

to maintain contact (mainly by telephone befriending) with as many subjects as possible for as long as possible for the sake of the trial was mistaken and counter productive. This was one aspect of an atypical approach contrived to meet the demands of scientific research.

Nevertheless, I have no doubt about the value of specialist nurses in providing continuity of care and practical support. Helen Caulton describes the kind of complementary support that is being offered in cooperation with specialist nurses and clinicians. I am convinced that, after preparatory training, people who survive cancer can be effective befrienders to patients with similar diagnoses.

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- 1 McArdle JMC, George WD, McArdle CS, Smith DC, Moodie AR, Hughson AV, *et al*. Psychological support for patients undergoing breast cancer surgery: a randomised study. *BMJ* 1996;312:813-7. [With commentary by C Foster.] (30 March.)
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Gaining patients' consent

Description of orthopaedic operations is inaccurate in half of consent forms

EDITOR,—It is recommended that written consent meeting professional guidelines should be obtained before any operative procedure.¹⁻³ Often, this written consent is used as a final preoperative check on the site, side, or nature of the proposed procedure, and thus its accuracy is important.

We reviewed the accuracy of completion of consent forms in the orthopaedic department of a teaching hospital by examining a random sample of 180 such forms and their associated operative procedures. All inaccuracies, abbreviations, or faults in the operative description were noted. Legibility was not analysed, although the standard varied considerably. The faults were divided into three categories according to their seriousness, as follows.

Technical errors, where the doctor wrote the operative description in an abbreviated form but this posed little risk of the wrong operation being performed. Such errors included the use of single letters or abbreviations—for example, R or Rt (for "right") or ORIF (for "open reduction with internal fixation")—and # to indicate fracture.

Important errors, where the risk of the wrong operation being performed was increased but, owing to the form's obvious deficiencies, its reliability would have been questioned before the operation—for example, the operative procedure was incompletely described or the side or digit was omitted.

Serious errors, where important inaccuracy was found (for example, the wrong operation, side, or digit was written down).

Half of the consent forms were accurately and comprehensively filled in. The remainder contained one or more faults. When more than one category of error occurred the most important one determined the categorisation. The commonest fault—the use of single letters or abbreviations to denote the side of the proposed procedure—was found in 50 of the 180 forms. Abbreviations and the # sign were found in 36. The bone or side involved was not mentioned in 18. Two forms had serious errors: one patient had given consent for a procedure on his uninjured side and one for a different procedure from that which he had been told would be done.

These discrepancies remained undetected during the several preoperative checks. No errors in treatment or care occurred despite these serious faults.

An error rate of 50% is unacceptable, and the potential consequences of this level of inaccuracy are important. We would warn other surgeons of the dangers of using the consent form as a preoperative and peroperative guide to the proposed procedure and strongly recommend increased supervision of junior doctors when they gain patients' consent.

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- 2 Palmer RN. *Consent, confidentiality, disclosure of medical records*. 5th ed. London: Medical Protection Society, 1985.
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Telling parents all relevant details might reduce recruitment of children to trials

EDITOR,—Charlotte Williamson argues that patients in clinical trials have "the right to know all relevant details about the situation in which they find themselves."¹ If the investigators seeking consent can truly tell the patient that they do not know which treatment is better then there is not a problem. Often, however, such equipoise does not exist because the investigators suspect that one treatment is superior but a randomised controlled trial is still necessary. If the investigators share their suspicions with the patient that one treatment may be superior then consent to randomisation may be less likely.

The Medical Research Council's trials of new treatments in childhood acute lymphoblastic leukaemia have been running since 1970. Recruitment now includes over 95% of all cases of acute lymphoblastic leukaemia diagnosed in the United Kingdom, and five year survival has improved from 25% to over 70%.² Similarly, the United Kingdom Children's Cancer Study Group has been running studies in other childhood cancers since 1978.³ The outcome in children is improved by their inclusion in a trial.⁴ Since 1985 the new experimental arms have had a better outcome than standard treatment for acute lymphoblastic leukaemia. Earlier studies were marred by difficulties with recruiting patients and decisions about closing the studies.

The demonstrable improvements in outcome have come about because clinicians preferred to run a series of trials rather than pursue treatments selected on the basis of individual clinical judgment. Nevertheless, should parents and children giving informed consent to enter a randomised controlled trial in 1996 be made aware that for the past decade the new experimental treatments have given better outcomes? Would this not constitute a "relevant detail,"¹ even though recruitment to current trials might be adversely affected? Might this result in parents responding that, yes, they agree that randomised controlled trials have improved the outlook for children as a whole but they still want their child to have the new treatment?

Parents often cannot weigh up clearly the unknown benefits of the trial treatment against known side effects, particularly when differences in morbidity between the two arms of the trial are considerable. Is it acceptable to argue that the common good will be served by including the child in a trial if uncertainty exists in the parents' minds, or should the parents and child be told of

the track record of the experimental arms over the past decade?⁵

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Effect of CSM's warning about safety of third generation oral contraceptives

General practitioners in England prescribed second generation pills instead

EDITOR,—On 18 October last year the Committee on Safety of Medicines issued its latest warning on the risk of thromboembolism associated with combined oral contraceptives.¹ It did this after becoming aware of three studies indicating that combined oral contraceptives containing desogestrel and gestodene were likely to be associated with around a twofold increase in the risk of thromboembolism when compared with those containing other progestogens. There was insufficient evidence to know whether norgestimate was also associated with an increased risk. Analysis of the (now published) evidence supports the stand that the committee took over desogestrel and gestodene.

Since the committee's warning, the Prescription Pricing Authority has monitored the use of oral contraceptives on a monthly basis. Use of third generation oral contraceptives containing desogestrel and gestodene fell dramatically: from accounting for about 55% of the total use and 70% of the total costs before the warning they accounted for about 12% and 23% respectively after it. The main change was towards pills containing levonorgestrel, which increased from

30% to 62% of the total use and 16% to 44% of the total costs. Norgestimate was not included in the warning, but its use increased from 7.3% of the total before the warning to 12.3% afterwards and its cost increased from 9.7% of the total to 23%. Figure 1 gives a breakdown of the hormonal contraceptives supplied in September last year (the month before the committee's statement) and February this year.

The average prescription for an oral contraceptive is for 4.5 months, which suggests that roughly equal numbers of prescriptions for three months and six months are supplied. After the Committee on Safety of Medicines' warning the average prescription was for 3.9 months, which suggests that prescribers were trying new products for a shorter period. Prescribing now seems to be returning to its previous pattern.

Because second generation pills are considerably cheaper than third generation pills the costs of oral contraceptives have fallen considerably, though total use has been maintained. Recently, the costs of some oral contraceptives have been increased.

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- 1 Committee on Safety of Medicines. *Combined oral contraceptives and thromboembolism*. London: CSM, 1995.

Contraceptive effectiveness may be being sacrificed for safety

EDITOR,—The Committee on Safety of Medicines recently published a statement about the increased risk of breast cancer associated with oral contraceptives.¹ Have the effects of previous alerts about the contraceptive pill been assessed to show their impact on choices in contraception? Research shows that women primarily choose a contraceptive for its effectiveness and lack of side effects.²

Recently, the Marie Stopes Centre in Leeds reported a rise in the use of condoms by women seeking abortion after the safe sex campaign of the early 1990s³; one possible interpretation of this trend was that women had been influenced in their choice of contraceptive by the huge publicity attendant on that campaign. The use and methods of contraception of women seeking abortion at the centre were surveyed over five years. The percentage of women not using contraception fell over time in direct relation to the rise in the use of condoms.

Figure 1 shows the change in the use of contraceptives by women seeking abortion from January to June for three consecutive years, 1994-6. These findings from the Leeds centre are part of a nationwide study being undertaken by Marie Stopes International. The proportion of women reporting that they used condoms for contraception at the time of unintended or unwanted pregnancy has increased, while the proportion not using contraception has fallen. A similar pattern was found in our previous study.³ Also, the proportion of women choosing to use condoms as their primary method of contraception after abortion has doubled.

No society can attain a situation in which abortion is not required, but the numbers of requests for abortion can be reduced with good provision of contraceptives.⁴ Bromham has highlighted the possibility that misleading information may prevent uptake of new methods of contraception,⁵ but are women also experiencing a reduction in choice in real terms and moving away from more effective methods that are

Fig 1—Change in use of contraceptives by women seeking abortion at one centre during January to June, 1994-6

already available to those methods with fewer perceived side effects but less contraceptive efficacy?

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Abortions increased by nearly 8% in Norway

EDITOR,—The number of women using oral contraceptives in Norway has steadily increased from about 140 000 in 1985 to 160 000 in 1994 (roughly 17% of fertile women). The recent reports of an increased risk of venous thromboembolism associated with third generation compared with second generation oral contraceptives received much attention in the media, and members of the Norwegian parliament demanded that health authorities should take action against the only third generation pill in Norway that contained desogestrel. Last November the Norwegian Medicines Control Authority issued a statement that this pill should be restricted to women who were dissatisfied with second generation pills; this led to a 75% decrease in the use of this particular pill and an 8% decrease in total pill use by late February this year.

In Norway legal abortion has been available on demand up to the end of week 12 since 1978. The annual numbers of these abortions were stable until 1988. Since then there has been a continuous decreasing trend from 15 800 to 14 500 in 1994. The annual number of deliveries has been in the range of 50 000-60 000 in the same period. All legal abortions are performed in public hospitals, each of which serves a well defined geographical area and population.

To study the possible impact of the media scare on the number of abortions we compared the abortion figures for January and February 1996 with those for the same period in 1995 in the nine largest hospitals in Norway (all have more than 2000 births each year; total 29 200 in 1995). With an annual number of abortions of

Fig 1—Use of various types of hormonal contraceptives in September 1995 and February 1996. Figures are numbers of patient months supplied