chemoprevention trials, a study of risk-reducing mastectomy or a study of breast screening by magnetic resonance imaging, whereas those not wishing to take part in any studies were offered annual mammography. Doing pretrial qualitative research, or, later, surveys of refusers or women who chose annual mammography, would have been extremely useful. Such research might perhaps show, for example, that some women opting for mammographic screening believe that screening is preventive, not diagnostic. Inadequate information, media hype, and endorsement by advocacy groups might contribute to women's faith in screening at the expense of the trial option.

Addressing core problems of poor information provision in all health-care areas, undertaking research endeavours owned by all stakeholders, not just the scientific community, might lead to fewer but higher-quality and more-relevant truly successful studies.

*Hazel Thornton, Mary Dixon-Woods

Department of Epidemiology and Public Health, University of Leicester, Leicester LE1 6TP, UK

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Sir—You discuss recruitment of women to clinical trials.[1] It has been often alleged that women are short-changed by medical research, so many times in fact, that most people, professionals and patients alike, now accept them as true. Specifically, people have stated that women are routinely excluded by medical research, and under-represented in the studies in which they were included.

Over the past 3 years, I have researched these claims,[2] and summarise my findings here.

In 1997, the director of the National Institutes for Health (NIH) Office of Research on Women's Health asserted that women were routinely excluded from medical research supported by NIH. Many others have made similar statements. In fact, the 1979 NIH Inventory of Clinical Trials lists 293 studies. 268 (91%) trials included men and women.[3] Of the remaining 25 studies, 12 included only men and 13 only women. Thus, women were included in 96% of clinical trials. In a MEDLINE search done with the sex-specific delimiters male or female, for most disorders, women were research participants in most medical research studies, including those done in the 1970s and 1980s.

The second criticism of NIH research is that when women were enrolled in trials, their numbers were inadequate. An analysis of 1989 enrollees in the National Cancer Institute Clinical Trials Cooperative Group Program reported 57% female participation,[4] even though men have a cancer death rate that is almost 50% higher than women. The analysis reported almost 40 clinical trials for breast cancer, compared with only ten for prostate cancer. Meinert and colleagues[5] reviewed all clinical trials published in five leading medical journals in the years 1985, 1990, and 1995. Overall, 550 743 women and 355 624 men were enrolled. Assessment by major disease categories showed that men were under-represented in cancer research, women in cardiovascular research, and men in all other disease areas.

Overall, women have, therefore, been fairly represented in most research areas. The perception before 1990 that women were unfairly treated by medical research, and the belief that health research therefore needed to play catch-up, formed the basis for much of the health policy for the two sexes in the USA over the past decade. The number of NIH studies of women only overtook the number of those of men by a three to one margin by 1997. As a result, overall male participation in NIH extramural research fell to 32% in 1997.[5] Yet, ironically, men have historically been less likely to have health insurance, to have a regular source of medical care, or to seek care when they get sick. In most areas, men's lifestyle risks are greater than those of women. And US men die 5·7 years earlier than US women.

We need to reconsider the widely held, but largely incorrect, assumptions of the past decade. Certainly, improvement of women's health must continue, but aren't men equally deserving of good health?

Edward E Bartlett

School of Public Health, George Washington University, 2175 K Street, Washington, DC 20037, USA

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4 Ungerleider RS, Friedman MA. Sex, trials, and datatapes. *J Natl Cancer Inst* 1991; **83:** 16–17.
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Sir—You point out the difficulties in enrolling women to clinical trials and the resultant problems in providing evidence-based health care.[1] The problem is greater in children, for whom suitable trials might not be instigated in the first place and off-label and off-licence prescribing of drugs is, therefore, common.[2]

The Griffiths Report into a trial of negative pressure ventilation in neonates suggested that research involving children should be more closely supervised than other research, resulting in well-meaning discrimination against children.[3] Hence, there are obstacles to the setting up of such clinical trials and to enrolment of children once the trial is in progress.

We are involved in a multicentre trial, comparing once daily with three times daily tobramycin in patients with cystic fibrosis.[4] This study is enrolling male and female children and adults at 14 centres in the UK. Submissions have been made to the Trent Multicentre Research Ethics Committee and 15 other local ethics committees. So far, 137 participants have completed treatment per protocol, of which 66 (48%) are children younger than 16 years. 69 (50%) participants are female. We believe these numbers are a representative subset of the UK cystic fibrosis population. Of those patients entered on the UK cystic fibrosis database, 55% are younger than 16 years and 54% are male.

Enrolment depends on enthusiastic local investigators who receive no direct remuneration for entering patients into the study. Their support has been maintained through regular reports and local investigators' meetings. The views of patients on their experience of the trial process have been sought and published in the Cystic Fibrosis Trust newsletter to aid enrolment. Finally, the Cystic Fibrosis Trust (the study's sponsor) has added its support by encouraging patients to volunteer for the study and local investigators to be proactive in enrolment.

We believe representative involvement of women and children in clinical