groups in Wald and colleague's study would be useful.

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1 Wald NJ, Murphy P, Major P, Parkes C, Townsend J. Frost C. UKCCCR multicentre randomised controlled trial of one and two view mammography in breast cancer screening. *BMJ* 1995;311:1189-93. (4 November.)

Many subjects in trial were not asked for consent

In the UKCCCR multicentre randomised controlled trial of one and two view mammography in breast cancer screening, only one out of the nine breast screening centres that took part sought informed consent before randomisation from the 40 163 women attending their first breast screening examination who participated in this trial.[1] The remainder sought consent after randomisation and only from those women who had been allocated to either of the two view arms (ratio 1:1:2)—that is, a quarter of the women in eight out of nine centres did not know they were in a trial.

Might it be assumed that the trial working party decided this because consent is not sought from women "invited" for breast screening? Presumably it was deemed to be unjust to those millions of women who have attended for mammographic screening without benefit of the provision of adequate balanced information that informed consent would confer. Should we not now be asking if it was unjust and unethical for those women in this trial not asked for consent, particularly as the stated conclusion that "two view mammography is medically more effective than one view: it detects more cancers and reduces recall rates; it is also similarly cost effective financially" could hardly be said to be counter intuitive?[2-5]

Is it not time that all women who attend for screening are presented with proper, balanced information and asked for consent? It would be particularly interesting to know the opinion of the 9000 or so unsuspecting women who unknowingly participated in this trial. Such better informed women would be better placed to enter into the debate concerning the value (economically and psychologically) of screening in terms of reducing the morbidity and mortality of women with breast cancer.

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Redefining marginal costs and benefits

EDITOR,—The results of the study by Nicholas Wald and colleagues[1] indicate that two view mammography is more effective in detecting breast cancers than a single view technique, but as it is more expensive there is little difference in average costs per cancer detected by these two methods. The "marginal" cost of two view screening has been taken to be the difference in average screening costs divided by the difference in the number of cancers detected by each method. In the context of this study, the marginal benefits of two view mammography are the extra cancers detected and the marginal costs are the extra expenditures incurred in their detection. Thus the true marginal cost of the two view method is the difference in total costs of the techniques divided by the difference in the number of cancers detected.

Furthermore, although costs are incurred at the time of screening, benefits (years of life saved) accrue over several years. The authors might therefore have considered the process of discounting in their calculation of costs per year of life saved.

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High detection rates do not necessarily lead to lower mortality

EDITOR,—The finding of a substantially higher rate of detection of breast cancer by two view compared with single view *x* ray mammography in the well designed randomised clinical trial by Nicholas Wald and colleagues deserves comment.[1] The assumption in the authors' four key messages that high detection rates will lead to larger reductions in mortality from breast cancer is not borne out by evidence from the randomised controlled trials summarised by Fletcher *et al.*[2] The Health Insurance Plan trial detected 2·7 cancers, the Malmo trial 7·5 cancers, and the Edinburgh trial 6·2 cancers per 1000 women, but as the reduction in mortality produced was 29%, 19%, and 16%, respectively, the higher detection rate did not lead to the most favourable outcome in terms of reduced mortality.

Benefits of a screening programme rest on other factors also, including diagnosis and treatment. Britain does not have the highest incidence of breast cancer but has the highest mortality from the disease. It seems that life expectancy can be extended only in a proportion of cases. On the other hand, some detected cancers will never become life threatening if left alone.

The 24% increase in detection implies that the sensitivity (with one view as used until recently in screening in Britain) has been at best 76%; this is also consistent with the report of unexpectedly high rates of interval cancers (82% of the underlying incidence) in the third year after the start of the screening programme in Britain. Two view mammography is reported to miss 16·5% of palpable cancers; we therefore estimate that the overall sensitivity of the British programme to date will have been about 65%. Thus 35% of women with cancer who accepted an invitation to screening have been given false reassurances. This will have led to delays in management of some women with invasive disease.

The fact that these trial results have appeared some seven years after the inception of the screening programme supports the views of Skrabanek, Jatoi and Baum, and Rodgers that women should be given the fullest possible information on the uncertain balance between risks and benefits of the screening and then, if they agree, sign a consent form.[3-5] Even if the basic hypothesis of screening—that early detection leads to increased expectancy for a small subset of those screened—is correct, the results of this study into the methodology of mammographic screening, together with the problem of overdiagnosis and consequent overtreatment, show that the British programme is in effect a large scale trial operating in virtually uncharted waters.

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Authors' reply

EDITOR,—As A H S Lee and colleagues imply, cancers detected only by two view mammography would be expected to be smaller, but our data indicate that any difference is small. Tumour size was similar in women who had either one or two views. In the group which had two views (one interpreted by one reader and both by another) the median size of the tumours detected by one view only was 13 mm compared with 12 mm if two views were used.

The effectiveness of breast cancer screening has been well demonstrated in randomised trials, and our trial shows the advantage of two view mammography over one view. To perform a trial of two view mammography with mortality from breast cancer as the end point would be impractical and unnecessary. As randomised trials have shown that mammographic screening reduces mortality, the prevalence of cancer detected by screening is a sufficient end point in trials comparing screening methods. If two view mammography detects 24% more preclinical cancers than one view, given the evidence on tumour size, a similar proportionate effect on mortality would be expected. The absence of a simple relation between the prevalence of detected cancers and the proportionate reduction in mortality from breast cancer across different trials of screening confirms that the rates of breast cancer and the effect of treatment vary in different populations and at different ages. It does not mean that the effectiveness of screening in detecting cancers is unrelated to its effect in reducing mortality.

It is reasonable to seek consent to participate in research from individuals invited to have a treatment or procedure that departs from recommended practice. Because one view mammography was recommended practice, consent was obtained only from women receiving two views. This issue is unrelated to that of providing appropriate information to women attending for screening, which should be (and was) done routinely.

Sneh Bhargava and colleagues have misunderstood our economic calculations on the marginal cost of two view mammography. This was done in the standard way (the difference in total costs between one and two view mammography divided by the number of extra cancers detected) with the total costs based on the average costs of screening women by each method. The costs related to detecting a cancer at the time of screening, so