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LEADING ARTICLES

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MEDICAL PRACTICE

NEWS AND NOTES

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CORRESPONDENCE

Because we receive many more letters than we have room to publish we may shorten those that we do publish to allow readers as wide a selection as possible. In particular, when we receive several letters on the same topic we reserve the right to abridge individual letters. Our usual policy is to reserve our correspondence columns for letters commenting on issues discussed recently (within six weeks) in the BMJ.

Letters critical of a paper may be sent to the authors of the paper so that their reply may appear in the same issue. We may also forward letters that we decide not to publish to the authors of the paper on which they comment.

Letters should not exceed 400 words and should be typed double spaced and signed by all authors, who should include their main degree.

Informed consent

SIR,—Jonathan Glover's leading article (19 July, p 157) has drawn attention to the Medical Research Council's trial of immediate and deferred orchidectomy in prostate cancer, which has been criticised by certain national newspapers and the medical press in Britain and North America.[1]

These uninformed reports, which have caused considerable distress to patients with prostate cancer, some of whom have not been in the trial, have been initiated by articles in the March and April issues of the *Bulletin* of the Institute of Medical Ethics in which the editor, Dr R Nicholson, has stated, among many other things, that: "Old men . . . are being castrated without their informed consent, for the benefit of a trial . . . that is of little, and possibly no, scientific value." "This trial is too late . . . both the scientific understanding of prostatic carcinoma and its treatment have advanced to the point at which it is no longer certain that the patients in this trial are being offered the best treatment." "The MRC protocol does not require subjects to be told of the alternatives to castration . . . and it appears that none of them are given this information." "The MRC . . . is content that research carried out under its auspices should contravene all current national and international guidelines for the conduct of research on humans."

We wish to inform you that these claims misrepresent the facts concerning this trial.

Many, perhaps most, surgeons still treat all patients whose carcinoma has spread beyond the prostatic capsule. Orchidectomy is usually the treatment of choice in the United Kingdom. However, data described elsewhere (Handley RC *et al*, Second International Symposium on Prostatic Cancer, Paris 1986)[2] show that a significant number of British men with prostate cancer do not need treatment for their malignancy and for these patients a policy of deferred treatment is the most appropriate. Most patients do need treatment but it is not known if this is best given immediately or when disease progression occurs because the necessary comparative trial has never been conducted. We agree that this trial should have been done 20 years ago but it was not and, as a result, the question remains unanswered. It is thus even more important that the trial is conducted now.

The reason Dr Nicholson claims the trial to be too late is because of his belief that other treatments have superseded orchidectomy, in particular the introduction of luteinising hormone releasing hormone analogues and total androgen ablation as advocated by Labrie.[3] In this respect Dr Nicholson has allowed himself to be persuaded by the results of an uncontrolled study that are not supported by the randomised study of the European Organisation for Research and Treatment of Cancer or by the early results of the Canadian randomised trial that is testing the "Labrie hypothesis" (Beland F *et al*, British Association of Urological Surgeons and Canadian Urological Association meeting, London 1986). His suggestion that patients treated in the MRC trial are being denied the best treatment is unsubstantiated. Since it may lead some patients to believe that they are being treated inadequately his statement is probably unethical.

"Informed consent" is Dr Nicholson's main concern and was discussed in part in your leading article. It is true that the trial protocol allowed that some patients could be treated without detailed informed consent if in the opinion of the surgeon this was thought to be in the patient's best interest. This is in agreement with previous MRC guidelines that recognise "for example, to awaken patients with a possibly fatal illness to the existence of doubts about effective treatment may not always be in their best interest."

That this should be accepted by the MRC and the many ethical committees that have approved the trial does not contravene all current national and international guidelines for the conduct of research on humans. The Declaration of Helsinki states, "If the doctor considers it essential not to obtain informed consent, the specific reasons should be stated for transmission to the independent committee." The guidelines on the practice of ethics committees in medical research published by the Royal College of Physicians of London in 1984 state: "In general patients should be told that a trial is in progress and that they are being given the best available treatment or one which may be better or worse. Only under exceptional circumstances when it would cause more distress to reveal the nature of the experiment is there an argument for not telling the patients; however, this should be a deliberate decision taken as part of the ethical review."

Contrary to Dr Nicholson's belief, British urologists do talk to their patients about their prostate cancer and its treatment. The average British patient is 10 years older than his American counterpart and the awareness of cancer and discussion about treatment is different from that which is common in the USA. We accept that every patient has an absolute right to be informed but we also have to work in a world in which some patients do not wish to exercise this right and their families do not wish them to be told that they have prostate cancer. Even more do not wish to choose their own treatment from the several available, and the phrase "You decide what's best" is still to be heard from patients in prostate clinics, despite a diligent attempt by the urologist to explain treatment options and the desirability of inclusion in a randomised trial. It may be argued that such patients should be excluded from clinical trials but is it better that their treatment should be chosen by a surgeon's personal preference, with no more