

infection. Clearly, the use of other than contemporary random controls would be grossly misleading.

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SIR,—The recent increased medical interest in and public awareness of the concept of informed consent (2 April, p 1117) have arisen directly from a failure on the part of medical educators. How many medical school curriculums contain lectures on the ethics of medicine or on the more particular aspect of entering patients in studies, be they randomised or not? Like many parts of medical education—training an understanding and appreciation of the correct approach is expected to be gleaned by carefully observing one's peers. Basic common sense, maturity, a feeling of humanity towards one's fellow man in general, and a belief in the principle of truth plus some instruction as a student or postgraduate should be sufficient to produce doctors who will fully inform their patients.

No one should deny that every patient has the right to be informed about his medical condition and treatment to that level of information which satisfies him. I believe that the signing of a written consent form is an indictment on the doctor—does his senior trust him, do the patient's relatives trust him, and most importantly does his patient trust him without such written consent? The relationship should be such that written consent should not be necessary. Is the written consent merely a safeguard for the doctor to be used later if legal proceedings are taken against him? The idea of informed consent and honesty towards patients entering trials is paramount in the doctor-patient relationship, and replacing that nebulous intangible sense of trust with a form representing evidence that informed consent has been obtained devalues the age old doctor-patient relationship. But sadly this is the way of the world today.

Finally, unless this problem is tackled and rectified at source—that is, at medical school—there is still no guarantee that written informed consent will mean that the patient has had the facts fully explained.

Time to communicate, to inform, and to gain the patient's trust is more meaningful than a patient's signature on a consent form and I believe that the introduction of written consent will lead inexorably towards less, not more, information being imparted to the patient.

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SIR,—I found much to applaud in the thoughtful paper of the Cancer Research Campaign Working Party in Breast Conservation (2 April, p 1117). In particular, ethics committees should be instructed to put more emphasis on the proposed method of obtaining informed consent than on any other aspect of a research submission. I have only one disagreement and that is the working party's belief that since there is doubt in the doctor's mind (or he would not be proposing a randomised trial in the first place) he has an obligation to express that doubt to the patient, and thus explain that he cannot choose "the best treatment" for her particular case.

This is fraught enough when the procedure being tested is a surgical operation. Once the decision has been made the operation is done, and once the operation is done it is done. But what happens when the procedure being tested is a diet or some other change in lifestyle that requires the patient's cooperation not just at the time of decision but for years afterwards? Patients, like doctors, are human. Which of us could resist the temptation to switch from diet A to diet B, when neither can be shown to be superior and we are already sufficiently worried to volunteer for a diet in the first place? When diets are to be tested the patients must be kept ignorant of the alternatives and (human curiosity being what it is), if possible, they should also be kept ignorant of the fact that an experiment is under way. Too much law can be bad for health.

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SIR,—Dr Iain Chalmers and Dr Adrian Grant (16 April, p 1279) describe as false the antithesis between the "rights of individuals" and the "demands of scientific research." Consider, however, a manufacturer who markets products only after the most stringent scientific testing and who suppresses a new drug after properly conducted clinical trials have showed an unexpected hazard. A patient would have been exposed to that drug only if he had agreed to take part in the trial and had been randomly allocated to the group receiving it. That the design of the trial met the highest scientific standards affords him no protection from an unanticipated risk.

Such hazards to patients are potentially present whenever novel procedures and products are being tested clinically; and there is always a potential conflict between the interest of subjects and scientists. Careful observance of ethical standards, including informed consent, is therefore important for the protection of both research workers and patients. That new methods and medicines may be introduced after unsatisfactory tests, or no tests at all, while it raises other ethical problems does not excuse those working to high scientific standards from the scrupulous observance of ethics. To express it more generally: the fact that science is a pursuit of the truth does not mean that its methods necessarily accord with the right and the good.

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### Poor prognosis of childhood acute lymphoblastic leukaemia

SIR,—We support the conclusion of Dr A Oakhill and Dr J R Mann (12 March, p 839) that social status is one of the important prognostic factors in childhood leukaemia.

During the last seven years we have treated 317 children with newly diagnosed acute lymphoblastic leukaemia with ages ranging from 2 months to 17 years (median five years). The ratio of boys to girls was 1:7. Complete remission was induced in 228 (72%) with a combination of prednisolone and vincristine. By the addition of a third or more agents remission was obtained in another 37 (12%), bringing the total remission rate to 84%. The 265 patients who achieved remission were given cranial prophylaxis (2400 rad cranial radiation and five doses of intrathecal methotrexate). Since 120 (45%)

either did not keep their further appointments or received irregular chemotherapy maintenance treatment (6-mercaptopurine and methotrexate with doses of prednisolone and vincristine every two months) could be given to only 145 patients regularly. Relapse occurred in 55 (38%) of these patients within 2 to 29 months. Seven children died from infection during their remission. Treatment could be discontinued in only 15 (10%) of the patients who stayed in initial remission for three years. The mean duration of remission of our patients was 17.6 months.

Our results are strikingly different from those obtained in developed countries. Most of our patients came from small villages where socio-economic conditions and the nutritional state of the inhabitants are very poor. Despite using the chemotherapy regimen which results in a five year leukaemia free survival in half of children with acute lymphoblastic leukaemia,<sup>1</sup> the prognosis of our patients with acute lymphoblastic leukaemia was very disappointing.<sup>2</sup> The outcome was also worse in our patients with acute myeloblastic leukaemia.<sup>3</sup> We believe that one of the poor prognostic factors in childhood leukaemia in Turkey is related to the poor social status of our patients. In fact more than half of the patients whose treatment could be discontinued came from families whose social classes were considerably higher than those of the other patients with acute lymphoblastic leukaemia.

Our results indicate that socioeconomic conditions are important in obtaining good results in childhood leukaemia and, as proposed previously,<sup>4-6</sup> poor social conditions should be considered as one of the poor prognostic factors in childhood leukaemias.

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<sup>1</sup> Simone JV, Aur RJA, Hustu HO, Verzosa M, Pinkel D. Combined modality therapy of acute lymphocytic leukemia. *Cancer* 1975;35:25-35.

<sup>2</sup> Hıcsönmez G, Ozsoylu S, Yetgin S, Zamani V, Gurgey A, Atahan I. Prognosis in 262 Turkish children with acute lymphocytic leukemia. *Turkish J Pediatr*, 1982;24:159-67.

<sup>3</sup> Hıcsönmez G, Gurgey A, Suloglu G, Yetgin S, Ozsoylu S. Acute myelocytic leukemia in children. *Turkish J Pediatr* 1978;20:63-70.

<sup>4</sup> Walters TR, Bushore M, Simone J. Poor prognosis in Negro children with acute lymphoblastic leukemia. *Cancer* 1972;29:210-4.

<sup>5</sup> Pendergrass TW, Hoover R, Godwin JD. Prognosis of black children with acute lymphoblastic leukemia. *Med Pediatr Oncol* 1975;1:143-8.

<sup>6</sup> McWhirter WR, Petrie G, Smith H. Childhood cancer and pregnancy drugs. *Lancet* 1981;ii:1051.

### U100 insulin and insulin absorption

SIR,—Dr P G F Swift and others (26 March, p 1015) suggest that variability in subcutaneous insulin absorption "may be mediated by effects on subcutaneous blood flow, insulin having a vasoconstrictor action." Our work, to which they refer in this context, in fact concluded that insulin injected subcutaneously had a local vasodilator effect.<sup>1</sup> The confusion may have arisen from Binder's article,<sup>2</sup> which they also cite, in which vasoconstrictor activity is attributed to insulin, although no direct evidence is presented to support this claim. Binder interpreted initial flattening of the disappearance curve of <sup>125</sup>I-insulin from subcutaneous injection sites as representing a phase of slow absorption, even though the precise relation of such disappearance curves to insulin absorption is uncertain.<sup>3</sup> By analogy with substances as diverse as atropine, bradykinin, vasopressin, and angiotensin,