

to her menses. She had two mild episodes of depression lasting some months and requiring chemotherapy. Her work record has not been as good as it was pre-accident. She terminated her engagement and has had some contact with new boyfriends, but no lasting relationship.

Her legal advisors requested some indication of the prognosis for mania following head injury or road traffic accidents. A search of the literature failed to reveal hard facts upon which to base the medico-legal report. This was surprising in view of the amount of literature available on depression and head injury. I would be grateful, therefore, if your readers could either through your columns or by direct correspondence acquaint me with a prognosis of the cases of mania following road traffic accidents of which they have had knowledge and experience.

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INFORMED CONSENT—OR THE UNWITTING PARTICIPANT

DEAR SIR,

In his paper on informed consent (*Journal*, October 1983, 143, 416–8) Max Hamilton states that it is a product of the anti-medicine movement, comprising material that patients mostly don't understand, so here "the nonsense enters". And "if it is meaningless in the clinical situation, it is equally so in a clinical trial". In summary, he is no advocate of it. However, there is another side of the medal that he did not discuss.

First, evidence before a court, followed by a lengthy discussion in the *Lancet* in 1982, showed the necessity of obtaining informed consent. Professor Hamilton must have overlooked this discussion. It concerned the death of a 84-year old widow following bone marrow suppression induced by 5-FU after an operation for carcinoma of the rectum. The efficacy of 5-FU was tested by means of an infusion via the portal vein. This patient had not been asked informed consent; she was an unwitting participant in this potentially dangerous randomised controlled trial, as were other participants (Brahams, 1982).

Second, experimenting doctors can have conflicting interests. There are personal interests, of financial or scientific origin (status, promotion, funds), and there are patient-directed goals. These interests may clash, and personal reasons for conducting research may override the obtaining of informed consent, as I have found.

Third, the World Medical Association adopted the Declaration of Helsinki (1964, revised in 1975 in Tokyo) and approaches this problem also from the standpoint of patient protection. The main effect of the Helsinki Declaration is the setting up of an independent committee to consider, comment on and guide research proposals (para. 1.2) and the insistence on (preferably written) informed consent. The UNO covenant concerning Civil and Political Rights also prohibits medical experiments without consent (art. 7), but is not applicable to the USA, which has not yet ratified it.

Fourth, contrary to Hamilton's suggestions most patients do seem to want to know as much as they are able to understand about their treatment and the alternatives; surveys showed that "people have a universal desire for information, choice and respectful communication about decisions" (Caplan, 1982). They expected to have as much information about their treatment options as physicians could reasonably be expected to provide.

Fifth, it is my opinion that any investigation or treatment that is not an accepted norm in medical practice may fall outside the "consented area". Then, obtaining informed consent becomes necessary. Ethical committees should not be able to substitute their permission for that of the patient, as is the case now according to the Helsinki Declaration (Kemperman, 1982). If the patient is not capable of understanding the basic plan of management, he or she should be excluded from the trial. The patient should have the initial responsibility, even if he or she may show later on the wish to delegate it.

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PSYCHOSIS AND ANTIDIURETIC HORMONE

DEAR SIR,

There are certain features of Lever and Stansfield's report of a patient with Addison's disease, psychosis and the syndrome of inappropriate secretion of antidiuretic hormone (IADH) (*Journal*, October 1983, 406–10) that we feel merit further comment.

First, in attempting to explain the development of