reassured that routine checks are now carried out in all industry sponsored clinical trials in order to detect made up or fraudulent data.

It is expected that in the not too distant future large multicentre trials will be scrutinised by a lead ethical committee in several centres throughout the UK before being referred to local ethical committees who will have the power only to accept or reject the trial, but not to modify the protocol. The time and cost to develop new drugs has hitherto been delayed by the need to have multiple modifications of protocol procedures because of the large number of committees which individually approved such studies.

It was agreed that as a routine doctors involved in clinical trials should be advised to ensure that they have proper cover from their medical insurance society because the indemnity provided by Trusts may not be sufficient. It might be expected that most pharmaceutical companies would be prepared to pay any increase in insurance which was required for doctors participating in such clinical trials. Pharmaceutical companies cannot be expected to indemnify doctors against their own negligence. For clinical practice this is currently covered by the obligation of the Trust but this may not be so in the case of clinical trials.

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Alternatives to district general hospitals?

Sir: The Department of Health (1996) claims that "Acute treatment does not have to be located on District General Hospital sites . . .". Alternatives to district general hospitals are cited and include developments in Stoke-on-Trent. We have consultant responsibility for these innovative beds in Stoke-on-Trent and would view them as complementing district general beds not replacing them.

We each have eight PIR beds in a purpose built bungalow attached to a community mental health resource centre and over a population of 80 000. Conceptually the main use of these beds is the prevention of further deterioration in mental health, short admissions aimed at intervention and respite care. It was also hoped that being local, accessible and not hospital based they would be more user friendly than traditional beds. While the PIR beds meet some of these objectives they cannot fulfil all the roles of traditional district general beds. Some of the problems encountered have been logistical and include out of hours medical cover, provision of pharmacy services, security and nursing staff levels. More importantly, at least 10% of patients are returned urgently to the district general unit, usually due to deterioration in their mental state or physical condition. Patients are not admitted directly to the PIR beds unless they are known to the service and present no apparent risk of suicide or violence.

At present we are investigating the clinical and cost effectiveness of these beds in comparison with district general beds and until our results are available we would advise caution in the belief that other forms of psychiatric bed provision can replace the district general.

DEPARTMENT OF HEALTH (1996) *The spectrum of care. Local services for people with mental health problems.* Wetherby: DOH.

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Use of Section 17 trial leave

Sir: I disagree with James *et al* (*Psychiatric Bulletin*, **20**, 201–204) that it is proper for Section 17 leave to be used in the manner described in their paper. The main advantage that they give for use of Section 17 as opposed to Section 19 is that it ensures the continuing involvement of the local hospital and ensures that patients are transferred back to their hospital at the earliest opportunity. The suggestion, therefore, is that consultant colleagues will not act in the best interest of patients unless there is some external legal requirement for them so to do.

It seems strange that at a time when a patient is at their most distressed and disturbed they are sent to a hospital where they will be under the care of a consultant who is not their Responsible Medical Officer, i.e., a doctor who is not authorised to assess a patient's ability to consent to medical treatment, to alter their medical treatment, to authorise trial leave and so on.

The very word 'grant' implies that the leave is with the approval of, if not at the request of, the patient. I am unsure if this would always apply when a patient is transferred from an ordinary hospital to an Regional Secure Unit.

Finally, it is usually considered appropriate to recall a patient from leave when it is necessary in the interest of the patient's health or safety or for the protection of others because the patient has failed in some way while on leave. The notion of recalling a patient from leave on the basis that the leave has been successful is somewhat unusual.

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