Correspondence

The dangers of the supervision register

Sir: The Secretary of State for Health announced in December 1993 a requirement that mental health providers establish and maintain supervision registers which identify those people with a severe mental illness, or diagnosed personality disorder who may be of significant risk to themselves or others. In February 1994 document HSG (94) 5 was sent out which outlines the requirements of the supervision register.

I am concerned about certain aspects of the supervision register which I have outlined under three headings.

Ethical issues

I am concerned about the effect of the supervision register on the role of the psychiatrist. The psychiatrist will now become an agent of the state with powers to put patients on a register which will be kept on a computer databank. There is a danger that this list could be used for other purposes. This clearly occurred in a case of HIV testing where patients applying for work, life insurance or mortgages were asked if they had been tested. It is likely that applicants will now be asked if they have ever been placed on a supervision register.

Psychiatrists will have to inform patients that they will be placed on the register. There is no official right of appeal as with the Mental Health Act. Just think what damage this will do to the doctor/patient relationship. Patients will hardly be likely to come forward and confide their suicidal and perhaps homicidal thoughts, and place their trust in their doctor. In some cases psychiatrists will be placed at risk due to the possibility of reprisals by patients with paranoid symptoms or sociopathic traits.

Practical problems

Setting up the supervision register will involve a tremendous amount of extra work to an already over-stretched service. Special review meetings will need to be set up, there will be extra paper work and patients will need to be informed. The document states that "patients should be informed orally and in writing when they are put on a supervision register and broadly told why they have been placed on it, how the information on the register will be used, to whom it may be disclosed and the mechanisms for review". Additional multidisciplinary review meetings will have to be set up and the patient will have the right to request a removal from the register, necessitating further review meetings by the clinical team.

Funding issues

Where are the extra professionals and services required to set up and police the register? Where are the additional community psychiatric nurses, social workers and psychiatrists? Where is the money to provide them? Across the country trusts are reducing funding for mental health services, and increasing demands are being made on a contracting service. What will actually happen in regard to the supervision register is that money will be moved away from existing clinical services in order to run the register.

Finally, I would argue that there is now a suitable and adequate method of supervising and monitoring patients at risk, the Care Programme Approach. The aim of the Care Programme Approach is to work together with patients with their agreement. The supervision register adds a different dimension to this approach which is more to do with responsibility and attaching blame rather than benefiting patient care.

R. D. ADAMS, *Bootham Park Hospital, York YO3 7BY*

(See pages 385–388–ed.)

Implications of the Calman Report

Sir: I welcome the debate which is occurring about the implications of the Chief Medical Officer's (Calman) Report on Specialist Training.

However, I think that Dr Kisely is misleading your readership in suggesting that "the Colleges of other medical specialties in Britain may soon require only five to six years of training" (*Psychiatric Bulletin*, May 1994, **18**, 309). My understanding of the work which is in hand in other medical Royal Colleges is that five to six years of *specialist* training is being considered, following a period of general professional/basic specialist training of one to two years.

In relation to the stipulation of the Royal Australian & New Zealand College of Psychiatrists' requirement for five years training in

psychiatry, presumably this relates to the nature of the posts for which that College is training its juniors.

It is essential in our reflection on the Chief Medical Officer's report that we bear in mind the requirement to train most juniors in our specialities for consultant work in the National Health Service.

F. CALDICOTT, *President, Royal College of Psychiatrists*

Election to Fellowship

Sir: While looking at the list of new Fellows (*Psychiatric Bulletin*, April 1994, **18**, 253), it occurred to me that it may be useful for prospective applicants for fellowship to know the proportion of applicants to fellowship elected by the Court of Electors.

Would the College be prepared to disclose and publish this information as in membership examination results, e.g. "Out of x number of applicants to the fellowship, y number of applicants were approved by the Court of Electors".

ANIL KUMAR, Calderstones NHS Trust, Whalley, Clitheroe BB7 9PE

Sir: Dr Kumar's suggestion is very interesting and I will certainly take this to the next meeting of the Court of Electors who should have the first opportunity to discuss this.

VANESSA CAMERON, *The Secretary, Royal College of Psychiatrists*

Post marketing surveillance studies

Sir: The Research Committee statement on post marketing surveillance studies (PMS) (*Psychiatric Bulletin*, February 1994, **18**, 115–116) contains much valuable information. It is unfortunate, however, that the committee bases its review on the 1988 PMS guideline which was superseded in 1993. The new 1993 guideline incorporates a number of significant additional clarifications and requirements.

(a) The terminology describing such studies has been clarified. Studies designed primarily to collect safety information, in which medication is prescribed according to data sheet indications (or studies which by their size alone add significantly to the safety database) are now called Safety Assessment of Marketed Medicine studies (SAMM). By contrast, trials involving marketed medicines having other primary objectives (e.g. blinded comparator studies or trials in new indications) are now called phase IV studies (phase V in the *Bulletin* article). Separate guidelines have been published for the conduct of phase IV studies. Although a single study might meet criteria for both SAMM and phase IV definitions (and must then meet the conditions laid down in both guidelines), the terms are not synonymous as is suggested in the *Bulletin* articles.

(b) In future, the Medicines Control Agency (MCA) will review and expects to be able to comment on all aspects of SAMM study design. Liaison between sponsor company and the MCA will also cover initial communications between the company and medical practitioners. By this process the scientific rigour of the protocol and the nature of the agreement between sponsor and investigator will be open to the scrutiny of the regulatory body.

(c) The company is required to update the MCA on the progress of the study every six months. A final report must be submitted to the regulatory authority within three months of study completion. It is also expected that SAMM study results will be published in the scientific literature.

(d) The sponsor company is expected to have a rigorous process in place for the prompt collection and reporting to the MCA of appropriate adverse events (within 15 days for serious suspected adverse reactions, at study completion for minor reactions and other events).

The recent update is clearly aimed further to ensure both the scientific quality and rigorous conduct of safety studies involving newly marketed medicines. Copies are available from the Association of the British Pharmaceutical Industry (ABPI), 12 Whitehall, London SW1A 2DY.

Recent reports of blood dyscrasias associated with the use of novel antipsychotic drugs have highlighted the importance of SAMM in psychiatry. Debate surrounding this issue has been hindered by a lack of reliable data for older agents (Kerwin, 1993). Safety studies of novel psychotropic drugs will be important in the future. While the past conduct of such studies is rightly open to criticism, it will be important that practitioners have confidence in a future system which encourages safety assessment carried out in a proper scientific context. Familiarity with the additional safeguards incorporated into the new guidelines should be part of the confidence-building process.

KERWIN, R. (1993) Adverse reaction reporting and new antipsychotics (1993) *Lancet*, **342**, 1440.

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