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CORRESPONDENCE

Correspondents are urged to write briefly so that readers may be offered as wide a selection of letters as possible. So many are being received that the omission of some is inevitable. Letters must be signed personally by all their authors.

Drug firms' co-operation in clinical trials

SIR,—As an active clinical trialist running a clinical trials unit I wish to draw your attention to a major problem which we are beginning to encounter with certain drug firms. This is an unwillingness of one firm to provide matching placebo and active drugs for other firms wishing to carry out drug trials using these drugs as comparative agents.

I believe this is a major problem because the actual agent used, if not provided by the firm which makes the drug, may not correspond to that drug's biological profile. What is happening is that drug firms are producing their own versions of the active agents and are relying on biological dissolution time as sufficient evidence of equivalent biological activity. To my mind nobody has yet shown a direct correlation between biological dissolution times and bioavailability, and it is very hard, therefore, to rely on biological dissolution times without the bioavailability studies. Clearly it is a major undertaking for any drug firm to carry out biological availability studies on another firm's compounds, and yet this may become necessary if firms are not willing to co-operate with each other.

Very few clinical units are able to carry out estimations of the blood levels of active drugs. We are perhaps lucky in this respect at this hospital, where we can do this, but it would mean an awful amount of extra work if we were expected, every time we embark on a comparative trial, to carry out bioavailability studies on the drugs to make sure that we are using bioequivalent drugs. What is really worrying is the number of trials that have been carried out in the past using products which were not proved to be bioequivalent and this must call into doubt a lot of the published trials in, particularly, the rheumatological field.

It is perhaps the place of a clinician to point out to the drug industry that it is in its own interest to co-operate. Co-operation between the firms will produce better trials and at the end of the day the person who really matters, the patient, will be the one who will gain. I cannot see that any drug firm offering comparative drug material is going to be the loser because whatever happens their drug will be subjected to more papers and more expert assessment.

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Nursing shortages in NHS hospitals

SIR,—Your Briefing (15 July, p 222) draws attention to the facts underlying the shortage of clinical state registered nurses (SRNs) and much anger was voiced at the recent Annual Representative Meeting by those debating the motion "That this meeting is deeply concerned with the increasing burden of patient care that is placed upon an already overworked nursing staff and feels that there is an urgent and pressing need to increase the number of trained nursing staff who are directly concerned with the care of the patient."

As a general surgeon I have found nursing cover lacking at times, but my problem has been to quantify the situation and lay down criteria so that facts back up any decision to limit the service. To this end I have developed a points system where a sister equates to 6 points, a staff nurse to 5, a state enrolled nurse (SEN) to 4, a student nurse to 3, a pupil nurse to 2, and an auxiliary to one, with appropriate adjustment for part-timers. Using this scale I can look at the duty rota for nurses on the wards and total up the points for the week and act accordingly. So far I have applied myself only to day staff and for our wards of 25 acute beds at this hospital I consider a total of 25 points to be the lower margin of safety. I mention this only as a guideline, for each one of us should do this exercise and formulate criteria, which will obviously vary according to the number of patients and the specialties involved.

Following a recent disaster I now insist that, within the points system, there should be two trained staff on duty during all normal working hours—that is, when lists are in progress and the ward is admitting emergencies. This has become necessary because of the familiar spectacle of senior staff, loyal and committed, trying to cope but being unable to delegate as the staff under them are inexperienced, though sometimes numerically adequate. In this situation I hold that substitution of an SRN by an SEN requires an extra pair of hands on the ward, as I think pressurisation and turbulence—that is, moving nurses around in times of crisis—contributed to the event.

Central in your Briefing is the relative increase in staff other than clinical SRNs, and it is skill and experience that are now sometimes so lacking on the wards; meanwhile the numbers of student and pupil nurses oscillate