Local research ethics committees and multicentre drug trials

EDITOR,—The role of local research ethics committees in multicentre trials has been discussed at length in the *BMJ* and other journals. I understand the frustration of researchers at having to jump through so many hoops, but I sincerely hope that any central committees which do emerge reflect the practice of the best of the local committees and do not become a soft option for gaining approval for poor quality projects, either in hospital or general practice.

The ethics committee that I chair recently received a response from a major pharmaceutical company that shows scant regard for the carefully considered opinion of a local research ethics committee and a gung-ho attitude to ethics committee approval in general. The study in question was to compare antibiotics in the treatment of otitis media and chest infections in children. We coopted the expert opinion of a consultant microbiologist and on his advice wrote to the participating general practitioner, the following letter.

Dear Dr —

Re: A multicentre, open label, parallel group study in general practice of the comparative efficacy and tolerance of Orelox (cefepodoxime proxetil), Augmentin (co-amoxiclav), or Distacolor (cefaclor) in the treatment of otitis media and chest infections in children.

The ethics committee has carefully considered your protocol but was unable to approve it for the following reasons:

- (1) The inclusion criteria are extremely vague and most of the infections treated would undoubtedly be viral in origin.
- (2) Neither of the comparative drugs reflects the current recommendation for treatment of such infections in general practice in Leeds—that is, ampicillin.
- (3) Any data on bacteriological efficacy are likely to be very limited due to a combination of poor selection (see above) and poor techniques for microbiological sampling, with prolonged transport time to the central laboratory. Cough swabs are an extremely inefficient method of sampling lower respiratory tract secretions and an ear swab fails to sample the site of infection in otitis media in the absence of a perforated ear drum.
- (4) The list of causative pathogens in the protocol includes commensal organisms such as corynebacteria and viridans streptococci which are probably not pathogens in this setting.

The study seems to be of limited scientific value in an area where a good range of therapeutic options already exists. The vague criteria for patient inclusion are particularly worrying in view of the well recognised tendency to overprescribe antibiotics to children with these types of infection.

Yours sincerely

We would have been quite prepared to consider the drug company's response to these criticisms, which we believe are valid, and we would have been prepared to change our minds concerning approval if the problems could have been resolved to our satisfaction. However, instead of a substantive reply we received the following.

Dear Dr —

Re: A multicentre, open label...

Thank you for your letter concerning your ethics committee's consideration of our protocol.

I note your committee's comments on our protocol with considerable interest. Fortunately, there are

Advice to authors

We prefer short letters that relate to a recently published article and we are unlikely to publish letters longer than 400 words and containing over five references. Letters may be shortened. Your letters should be typed with double spacing and include a word count. All authors need to sign the letter and provide one current appointment and address. We encourage you to declare any conflict of interest. Please enclose a stamped addressed envelope if you require an acknowledgment.

sufficient LRECs [local research ethics committees] elsewhere in the country for us to be able to proceed with this study without the participation of Dr — as a trialist.

I understand that the Department of Health is currently engaged in drawing up new guidelines for local ethics committees in relation to their role in the consideration of multicentre studies. When this happens, we will hopefully see less of the failures of communication that have occurred during your consideration of this protocol.

I regret that this protocol submission to your committee has, in effect, been a waste of time. However, I would like to thank you for taking the trouble to give us your comments and look forward to doing business with you again in the future.

Yours sincerely

The only concern of the company seemed to be that its project would be allowed to take place in some centres. It appeared to show no interest in the valid questions that we posed, and we got the impression from the terms of its letter that it hoped that once there was a central committee the kind of objections raised by us could be put aside.

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Emergency care in general practice

Many general practitioners are unable to provide safe emergency care

EDITOR,—Anthony Avery and Mike Pringle's editorial on emergency care in general practice is a counsel of perfection divorced from reality.¹ The reality is that, no matter how well they are trained and equipped, many general practitioners are not able to deliver a safe level of emergency care to their patients. This is particularly true in inner city areas, where the pressure of work in the surgery often precludes routine visiting, let alone the possibility of abandoning overcrowded waiting rooms to attend emergencies. Heavy traffic and one way systems often compel general practitioners to perform house visits on foot. The threat of violence in many council estates in inner cities has led doctors to abandon their black bags, quite apart from defibrillators and electrocardiographs, to avoid theft. There is an urgent need for a nationwide reactive and effective emergency service, staffed by properly trained paramedics, to

respond to medical emergencies at home while general practitioners get on with the work in which they are expert.

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¹ Avery A, Pringle M. Emergency care in general practice. *BMJ* 1995;310:6. (7 January.)

British Heart Foundation recommends early defibrillation

EDITOR,—Anthony Avery and Mike Pringle emphasise the need for general practitioners to be adequately equipped and trained to provide optimal care in medical emergencies.¹ They emphasise the value of early defibrillation in the management of cardiac arrest, which in many cases could be provided by an appropriately equipped general practitioner. In recent years the British Heart Foundation has helped provide general practitioners with defibrillators, and the results show the value of this policy.

The foundation's records show that among 83 patients who suffered a cardiac arrest in the presence of a general practitioner equipped with a defibrillator, defibrillation was successful in 63. Fifty six reached hospital alive, of whom 47 were ultimately discharged home. In 71 cases the cardiac arrest had been either ventricular fibrillation or ventricular tachycardia and therefore potentially correctable. Defibrillation was often effective even when cardiac arrest had occurred before the general practitioner's arrival, particularly when it was attempted within 10 minutes of collapse. Eighteen of 36 patients who had received cardiopulmonary resuscitation from a bystander before the doctor's arrival survived to leave hospital. Even when cardiopulmonary resuscitation had not been given by a bystander, an appreciable proportion—seven of 33—survived when defibrillation was performed within the same time limit.

Our results show the importance of defibrillation provided by general practitioners. All front line ambulances should now carry a defibrillator, and our results endorse the British Heart Foundation's guidelines on managing patients with myocardial infarction.² These guidelines recommend a dual response by both the ambulance service and a general practitioner in such cases, so that a defibrillator is available as soon as possible.

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¹ Avery A, Pringle M. Emergency care in general practice. *BMJ* 1995;310:6. (7 January.)

² Weston CFM, Penny WJ, Julian DG, on behalf of the British Heart Foundation Working Group. Guidelines for the management of patients with myocardial infarction. *BMJ* 1994;308:767-71.

Carrying heavy equipment may be impractical

EDITOR,—General practitioners are exhorted to carry nebulisers, electrocardiographs, and defibrillators while on call.¹ How can I, a woman weighing 54 kg, be expected to carry an electrocardiograph

and a defibrillator as well as my medical bag up five flights of stairs in a block of flats, where the lift is invariably out of order or its floor swimming in urine? What do I do with the equipment while visiting patients who do not require it? If I leave it in the car the possibility of its being stolen is high. Have the authors considered the practical implications of their advice?

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1 Avery A, Pringle M. Emergency care in general practice. *BMJ* 1995;310:6. (7 January.)

Should be properly recognised

EDITOR,—The editorial on emergency care in general practice fails to mention the growing trend for many general practitioners not to provide prehospital emergency care for their patients—for example, emergency coronary care or care in asthma.¹ Other health care professionals, such as those in the ambulance service and midwives, are only too keen to take on this work to enhance their status. It is surely in the best interests of neither our patients nor the medical profession as a whole for us to lose, by default, what is an integral and rewarding part of general practice. The provision of effective emergency care requires proper contractual recognition, reward, training, equipment, and drugs.

We are surprised at the authors' suggestion that general practitioners should not waste time obtaining an electrocardiogram in patients with a suspected acute myocardial infarction and at their failure to mention thrombolysis before admission to hospital. The risk of developing a potential lethal cardiac arrhythmia is greatest immediately after the onset of infarction,² and all patients with a suspected acute myocardial infarction should be monitored electrocardiographically before and during transportation to hospital. It has been shown that the earlier a thrombolytic drug is given the greater the benefit,³ although this is controversial; the British Heart Foundation's latest guidelines recommend that a thrombolytic drug should be given before admission if the likely time from the initial symptoms to thrombolysis being given in hospital is more than 90 minutes.⁴

Perhaps the time has come when all aspects of prehospital emergency care, including the mechanisms for the most effective delivery of that care, need re-evaluation.

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1 Avery A, Pringle M. Emergency care in general practice. *BMJ* 1995;310:6. (7 January.)

2 Armstrong A, Duncan B, Oliver MF, Julian DG, Donald KW, Fulton M, et al. Natural history of acute coronary heart attacks. A community study. *Br Heart J* 1972;34:67-80.

3 GREAT Group. Feasibility, safety, and efficacy of domiciliary thrombolysis by general practitioners: Grampian region early trial. *BMJ* 1992;305:548-53.

4 Weston CFM, Penny WJ, Julian DG, on behalf of the British Heart Foundation Working Group. Guidelines for the early management of patients with myocardial infarction. *BMJ* 1994;308:767-71.

Irish general practitioners learn immediate cardiac care

EDITOR,—We agree with Anthony Avery and Mike Pringle that more courses on emergency care should be provided for established principals in general practice.¹ For the past two years we, in conjunction with the Irish College of General Practitioners, have been providing courses in

immediate cardiac care locally to Irish general practitioners. A local tutor from the college's continuing medical education faculty organises the administrative details (venue, facilities, catering, etc), and we provide the tutors and teaching equipment. The content of the courses is based on the recommendations of the American Heart Association² but is limited to prehospital concepts (for example, lignocaine is the only antiarrhythmic drug reviewed). A good ratio of tutors to participants—usually 1:4—is an essential part of the skills training in the course. The skills stations teach cardiopulmonary resuscitation, management of the airway, management of arrhythmias, and management of the cervical spine in cases of trauma. Finally, each participant, in conjunction with local ambulance staff, puts all these skills together during a simulated arrest.

To date, 235 practitioners—almost one eighth of all principals in general practice in the Republic of Ireland—have participated. Four fifths of participants have completed feedback forms; all described the course 'as useful or very useful'. The small group format, skills based components, and opportunity to practise with local ambulance crews have been especially appreciated. The original core group of three tutors has now expanded to 15. Most are principals in general practice, but a nursing tutor and ambulance service tutor also participate. All are trained in advanced cardiac life support to the American Heart Association's standard. Owing to the popularity of the course a similar course in immediate trauma care is now also being provided.

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1 Avery A, Pringle M. Emergency care in general practice. *BMJ* 1995;310:6. (7 January.)

2 American Heart Association. *Advanced cardiac life support: instructor's manual*. Dallas: AHA, 1994.

Courses are available

EDITOR,—Anthony Avery and Mike Pringle emphasise the importance of emergency care in general practice.¹ I commend to readers the certificate course in prehospital emergency care run jointly by the Royal College of Surgeons of Edinburgh and the British Association for Immediate Care (BASICS). The first course was held in March 1993. I recently attended one of these three day courses and found it an ideal way of updating and advancing my knowledge and practical skills in emergency care (trauma, medical, paediatric, obstetric); there was the added benefit of meeting the other participants (doctors, paramedics, and nurses). The course ends with a formal assessment. For further details of this course and other more advanced training by BASICS, readers should write to Dr J Scott, BASICS Education, 34A Woollards Lane, Great Shelford, Cambridge CB2 5LZ.

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General practitioners should be trained in cardiopulmonary resuscitation

EDITOR,—Anthony Avery and Mike Pringle's recommendations regarding emergency care in general practice are useful, but we cannot visualise

every general practitioner carrying a defibrillator, as well as all the other items mentioned, while doing his or her home visits.¹

As anaesthetists, we are constantly appalled at the lack of basic resuscitation skills of medical and nursing staff (senior and junior). Management of the airway is something in which everyone seems to fail horribly. If these findings are extended into general practice the management would be even worse as general practitioners see few collapsed patients. We believe that the Royal College of General Practitioners should alter the training programmes for general practice to include at least three months in anaesthetics. This could perhaps be incorporated with three months in acute trauma (orthopaedics). As Avery and Pringle mentioned, regular updates are extremely important in maintaining skills.

Recently we wrote to all our local general practitioners about the availability of training in cardiopulmonary resuscitation in our hospital. We extended this invitation to their nurses and receptionists. Nine months later the only response has been one telephone call. We believe that local tutors in general practice should encourage their fellow doctors constantly to improve the quality of service they provide to the local population; as well as cervical smear tests and well women clinics, constant updates in cardiopulmonary resuscitation should be essential.

This in no way is meant as a criticism of general practitioners, but in the present medicolegal climate we should all attempt to improve the care we provide to our patients.

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Antibiotics carried in general practitioners' emergency bags

Having a central supplier would increase carriage of drugs

EDITOR,—As part of a course for a diploma in therapeutics I carried out a survey of the drugs carried by general practitioners in 1994. I sent a questionnaire to all 304 course members, who were general practitioners in the areas covered by North Tyneside and Northumberland Family Health Services Authorities, asking about drugs and equipment carried; 193 questionnaires were completed in respect of antibiotics.

Interesting differences are evident between my findings and those of M J Colbridge and colleagues¹ and Ong and Dunbar² (table). Over the past six years carriage of ampicillin has fallen dramatically and that of co-trimoxazole and tetracycline less so. Carriage of amoxycillin and co-amoxiclav and of trimethoprim has risen. Carriage of benzylpenicillin has increased to 95%.

Just before Ong and Dunbar's survey in 1988 the chief medical officer advised all doctors to give parenteral benzylpenicillin before admitting to hospital any patient suspected of having meningococcal infection.³ To encourage doctors to carry benzylpenicillin general practitioners in the areas covered by North Tyneside, Northumberland, and Newcastle Family Health Services Authorities were supplied with free phials of benzylpenicillin. The availability of a free supply of samples and single dose sachets of many antibiotics is likely to be a potent factor in the selection of antibiotics for the emergency bag. In the late 1980s Beecham offered a monthly postal service, supplying sachets of ampicillin, and Wellcome similarly offered free