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Logistic regression models used in medical research are poorly presented

EDITOR,—The application of multiple regression models in medical research has greatly increased during the past years.¹ Nevertheless, assessing the accuracy of regression models in describing the data (goodness of fit) is almost unknown in medical research. Hence, medical journals may be publishing papers in which regression models are misused or results are misinterpreted.

We investigated the use of logistic regression in papers published in the *BMJ*, *JAMA*, the *Lancet*, and the *New England Journal of Medicine* during 1991-4. A Medline search using the strings logistic regression and proportional odds model yielded 111 papers. Of these, two articles stated the use of logistic regression in the abstract but the Cox model had been used instead. The remaining 109 papers used some kind of logistic regression. We investigated which kind of logistic regression was used (binary, polytomous, ordinal), whether a statistical reference and the computer software were specified, and whether a valid assessment of the goodness of fit of the logistic models² was reported.

Only one paper used the proportional odds model for ordinal response; the other 108 articles used binary logistic regression. A reference for logistic regression was specified in 48 papers, for the software in 57, and for both in only 26 papers. This is not in line with the guidelines of the International Committee of Medical Journal Editors.³ The most frequently specified reference was the book by Hosmer and Lemeshow,² followed by the book by Breslow and Day⁴ and various SAS manuals, while the most popular software packages in descending order were SAS, SPSS, BMDP, EGRET, and GLIM.

Goodness of fit was rarely assessed. Three papers stated the use of the Hosmer-Lemeshow test,² two compared the predicted and observed outcomes, and two reported the analysis of residuals. A further two reported the use of likelihood ratio statistics, but as the models contained continuous covariates the likelihood ratio test was inadequate.² Thus only seven papers reported a valid assessment of the adequacy of their regression model.

As the validity of all results and conclusions strongly depends on the goodness of fit of the models used, this practice of reporting is unsatisfactory and should be changed. We agree with Campillo that clear standardised publication criteria are needed to improve the current poor presentation of regression models in biomedical journals.⁵ We recommend that authors should always report the goodness of fit of regression models to avoid invalid results.

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Employing general practitioners in accident and emergency departments

Better to increase number of consultants in accident and emergency medicine

EDITOR,—Recent papers have studied the role of general practitioners in accident and emergency departments. The medical media have reported that employing family doctors in these departments may save £8 a patient.¹ Dale *et al* showed significant differences between the care provided by general practitioners and by junior staff working in accident and emergency for primary care attenders in an accident and emergency department.² When general practitioners were included as part of the accident and emergency team and saw all new attenders except those classified as having life threatening or urgent conditions they were found to manage these patients safely and to use fewer resources.³ It has also been shown that general practitioners manage primary care problems presenting to accident and emergency departments at reduced cost (£11.70) when compared with senior house officers (£19.30) and registrars (£17.97) in accident and emergency medicine.⁴

All these studies compared general practitioners who had had full vocational training with junior doctors training in accident and emergency medicine. The general practitioners had therefore completed their training in primary care, so one would expect them to provide better care than doctors still undergoing training. The new breed of vocationally trained consultants in accident and emergency medicine have an active role in the initial care of patients with both major and minor conditions in many centres. I have no doubt that consultants would show much better use of resources than their juniors: if they did not then what does training achieve? We have no comparative data for the care given by general practitioners and consultants in accident and emergency medicine.

Before accepting that the way forward is for general practitioners to work in accident and emergency departments we need evidence that this is preferable to an expansion in the number of consultants in accident and emergency medicine. Consultants have the advantage of being able to treat major as well as minor injuries.

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All doctors should spend time in general practice to learn skills of GPs

EDITOR,—I felt little surprise on reading Jeremy Dale and colleagues' paper comparing the cost effectiveness of general practitioners, senior house officers, and registrars in treating primary care patients in accident and emergency departments.¹ The authors conclude that employing general practitioners in accident and emergency departments offers a potential means of reducing the costs of treating patients with primary care problems. I, however, would suggest an alternative conclusion: that there is a compelling argument for hospital doctors—probably in all specialties—to spend a period in general practice learning some of the skills that seem to allow general practitioners to use clinical judgment rather than expensive investigations to assess patients with primary care needs.

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- 1 Dale J, Lang H, Roberts J, Green J, Glucksman E. Cost effectiveness of treating primary care patients in accident and emergency: a comparison between general practitioners, senior house officers, and registrars. *BMJ* 1996;312:1340-4. (25 May.)

Meaning of term "observational study" needs to be defined

EDITOR,—Is anyone else confused about the use of the term "observational study"? Nick Black uses it when referring to cohort and case-control studies,¹ whereas in last year's series of articles on non-quantitative techniques it was used to describe a qualitative social science research method.²

The development of evidence based medicine and critical appraisal skills encourages us to improve our understanding of the quality of evidence and the methods of health service research. I would find it helpful if the terminology for these two research techniques could be clarified. How about changing to the terms "analytical observational study" and "qualitative observational study"?

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General practice records should be kept on CDs

EDITOR,—Ian N Purves fails to address some important points in his editorial on the paperless general practice.¹

Firstly, how many of the practices that are now paperless have transferred all of their patients' old records to computer?

Secondly, how are records to be transferred from one practice to another when several different computer systems exist and the family health services authorities and health authorities must physically have the medical record envelope and its contents to effect a transfer?

Thirdly, when records are transferred the computer records will have to be downloaded into the medical record envelope in case the receiving doctor does not have a computer system or that system is incompatible with the previous general practitioner's.

Fourthly, what happens when the family health services authority or health authority cannot handle a transfer of records by computer because of incompatibility but the receiving general practitioner can?

Fifthly, what happens when the paperless records are only those made since the practice became computerised, so that a large percentage of the records is still held in Lloyd George folders? The records held on computer must then be printed out, and the thought of reams of A4 computer printout in a Lloyd George folder (which is smaller than A5) or of transferring records to disk just before sending them back is depressing.

Surely the answer is that the technology already exists but the investment would be enormous, although it would probably pay for itself in a very few years: all records could be held on a CD. The patient would keep a copy (prescriptions could be dispensed from it), the general practitioner would keep a copy, and another copy would automatically be kept on the family health services authority's or health authority's computer and backed up daily. Records could then be transferred in seconds, and access would be immediate no matter where the patient was. Hospital records (including moving images from investigations) could also be kept or could be transferred to these disks so that everyone always had the latest information on every patient. Thus every time a patient attended any general practitioner or hospital or had a prescription dispensed this would be recorded on the CD, and that record could be transferred to any other NHS record designated as appropriate. All that would be needed would be a countrywide network and double CD disk drive systems on every doctor's desk.

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Combining qualitative studies with randomised controlled trials is often useful

EDITOR,—Nick Black points out some of the limitations of randomised controlled trials but fails to mention that such trials rarely tell us why an intervention was successful or not.¹ Pharmacological studies may provide this vital information for drug interventions, but for other interventions, especially those that involve packages of services, randomised controlled trials are unlikely to do so. Black suggests that we should be open to using alternative designs, but he specifically excludes qualitative methods from consideration. We believe that approaches that combine randomised controlled trials with qualitative and quantitative studies of process are the best means of assessing whether such interventions work and why, thus increasing the generalisability of findings from randomised controlled trials.

We are currently undertaking a study of case management for people with serious mental illness. A formal randomised controlled trial has randomised mental health workers and patients to experimental and control groups, which receive a mix of services at differing levels of intensity (the UK800 case management trial). The trial is measuring and comparing outcomes between the two populations, but because of the complexity of the intervention and social environment it will not explain precisely how these outcomes are achieved. We are addressing

this question through a parallel study of process, using both qualitative and quantitative approaches, that has been designed to identify aspects of case management associated with positive or negative outcomes for patients. Outcomes are likely to vary within the experimental and control groups. Our study of process provides valuable opportunities for post hoc analysis of factors associated with positive and negative outcomes both within and between the study groups.

The uncritical application of randomised controlled trials in isolation from complementary methods may be one factor in explaining why health services research does not have an impressive record in influencing the development of mental health services. Combining randomised controlled trials with both quantitative and qualitative observational designs will generate information to help in the successful implementation of effective interventions in natural settings as well as allowing further refinement of interventions. The further that investigators move from the controlled environments of laboratories and clinics the greater is the burden of responsibility to make explicit descriptions of interventions and their implementation. It is important to understand that this can be a highly creative aspect of the investigation. Randomised controlled trials need not, and should not, merely "provide information on the value of an intervention shorn of all context."

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Evidence shows that cyclists should wear helmets

EDITOR,—We are disappointed to read that "Minerva is a keen cyclist but does not like wearing her helmet."¹ This is hardly the attitude towards injury prevention that we would expect from one who is such a proficient reader of the medical literature. We are concerned that this negative view might infect many of Minerva's loyal readers. Minerva expresses interest in an article from the *Journal of Medical Ethics* that argued that helmets should not be made mandatory until their use has been shown to reduce the rate of head injuries.² The article suggested that those who wear helmets may take greater risks during riding, thereby negating the protective effects of the helmet.

Convincing evidence exists, however, that bicycle riders who do not wear a helmet have a higher risk of head injury than those who do,³ which would take into account the effects of both riding behaviour and use of a helmet. Studies from the United States⁴ and Australia⁵ have shown substantial increases in the use of cycle helmets since the adoption of laws making the use of such helmets mandatory. Moreover, in the first four years after the legislation was adopted in Victoria, Australia, hospital admissions of cyclists were 40% below the number expected from trends before the legislation was adopted. In addition, the severity of head injuries among cyclists who were admitted to hospital fell after the law was adopted.⁵

On the basis of these studies the United States Centers for Disease Control and Prevention recommends, firstly, that cycle helmets should be worn by all people, of any age, whenever and wherever they ride a bicycle; and, secondly, that, to increase rates of use of helmets effectively, states and communities must implement programmes that include legislation, education and promotion, enforcement, and evaluation.³

Minerva grumbles that "No one wants people to be deterred from cycling, with all its health benefits." Does she have any data to show that laws that make the use of helmets mandatory cause a sustained decrease in cycling? Does she have any data to show that the health benefits of cycling outweigh the risk of serious injury if helmets are not worn? Minerva wants "robust evidence on which to base decisions." How robust must the evidence be when the benefits of wearing helmets are so patently obvious? What is the downside to wearing a helmet, other than the musing of Minerva's hair?

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Melatonin is available over the counter

EDITOR,—In an editorial on melatonin J Arendt states that melatonin is available in Britain "only on prescription on a named patient basis."¹ This is not true. Several months ago medical colleagues in Australia who had found melatonin useful for overcoming jetlag but impossible to obtain in Brisbane asked me to take some with me when I visited them. My local pharmacist directed me to the health food shop next door, where a new delivery of melatonin had just arrived amid claims that "this may be the last batch we get."

After reading Arendt's editorial I returned to the shop and found that the preparation I had bought previously was no longer available but that a new batch of melatonin in sublingual form was (60 tablets of 2.5 mg for £12.99). Although the contraindications listed on the container were extensive and the price prohibitive, melatonin is clearly selling well through at least one outlet in south east London.

Perhaps Arendt could clarify the current regulations regarding the sale of melatonin: is it illegal or merely undesirable to sell it? In the meantime, clinicians should be aware that some of their patients may have a supply of melatonin and be taking it.

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