supported by a report by the Department of Health and Social Security's working group on back pain, which analysed many papers on this subject in terms of scientific validity and found only three on manipulative therapy that fulfilled its criteria.² In general these studies are akin to asking "Is appendectomy an effective treatment for abdominal pain?"

Breen, a chiropractor, suggested that "for those who use manipulative therapy in the management of back pain patients, a clear idea of the nature of pain and its possible sources is of paramount importance."³ Furthermore, "without rational hypotheses to address these questions treatment becomes incoherent and irrelevant to the problem." By way of example, mechanical and local inflammatory sources of pain may be amenable to manual therapy, but infective, metabolic, neoplastic, and systemic inflammatory causes most probably are not. Indeed, it is quite possible that acute and chronic conditions, whether in the neck or in the back, will all respond in different ways. In keeping with Breen's view we believe strongly that any future attempt to rationalise the role of manipulative therapy in the treatment of back pain should be preceded by an attempt to classify and segregate both site and cause.

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- 1 Koes BW, Assendelft WJJ, van der Heijden GJMG, Bouter LM, Knipschild PG. Spinal manipulation and mobilisation for back and neck pain: a blinded review. *BMJ* 1991;303:1298-303. (23 November.)
- 2 Department of Health and Social Security. *Working group on back pain*. London: HMSO, 1979.
- 3 Breen A. Sources of back pain due to mechanical disorders within the lumbar spine: a chiropractor's view. *Proceedings of the Society for Back Pain Research* 1990 May:9-11.

AUTHORS' REPLY.—We are pleased that three of the letters discussing our review are written by authors of trials that we listed in our "top 10."¹ The detailed comments on the methods we used to assess published trials show the considerable advantage of this method of review. Whereas traditionally authors of review articles implicitly apply their (unknown) criteria, we explicitly formulated and used our criteria, which obviously facilitates discussion.

R S MacDonald states that the trial of Hadler *et al*² was greatly undervalued in the review, but this trial scored 53 points, which was the second best score. MacDonald applied our criteria and weighting to Hadler *et al*'s trial and ended up with 90 points. J A Mathews assessed a study of which he was a coauthor³ and also obtained 90 points. Both of these scores seem to be based on a different use of our criteria and the use of additional information that was not included in the original articles.

The statement that random allocation has been carried out is, in our opinion, not sufficient to warrant all four points for this criterion. All studies included in our review were randomised controlled trials. Studies could earn points if there was a clear description of how the randomisation procedure had been carried out. For readers this is important.⁴ The points given for sample size are not meant as a reward for sufficient power. Consequently we do not agree that points should be given depending on whether a certain difference in outcome was significant. Our main reason for giving points for large sample sizes was the assumption that with larger numbers one has more assurance that (un)known prognostic indicators will be equally divided between the study groups.

MacDonald's suggestion that all 10 points should be given for relevant outcome measures when an author reports only one or two primary outcome measures is certainly interesting. Of course these primary outcome measures should be

chosen (and preferably published) before the data from the trial are analysed. Otherwise the reader has no assurance that the choice of primary outcome measures was not guided by the data analysis.

T W Meade and colleagues performed one of the best studies,⁵ but it still showed severe shortcomings.⁶ They think that we insisted on pragmatic trials, but this is obviously not the case because studies were also rewarded if they included an adequate placebo treatment. Meade and colleagues claim points for having carried out an analysis based on intention to treat. In our review, however, studies could earn points for this criterion only if in cases of more than 10% loss to follow up (which was the case after two years' follow up) and an alternative analysis had also been carried out correcting for withdrawals and missing values.

We do not agree with Mathews that these kind of reviews can be carried out only by clinicians (although three of us are clinicians). As long as explicit criteria are used that can be applied and checked by most readers we see no ground for this statement.

We agree with S M Hay and B Todd that the design of studies of this treatment is probably difficult to improve. A recent study from our department scored 55 points when assessed by the two reviewers (GJMGH and WJJA, in this case not blinded) who had made the assessments in our meta-analysis.⁷ We still think, however, that further trials are needed to determine the efficacy of spinal manipulation and mobilisation for well defined subgroups of patients with back and neck pain. Although the methods of reviewing that we used clearly need to be developed further, we recommend them for reviewing past and future studies.

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- 1 Koes BW, Assendelft WJJ, van der Heijden GJMG, Bouter LM, Knipschild PG. Spinal manipulation and mobilisation for back and neck pain: a blinded review. *BMJ* 1991;303:1298-303. (23 November.)
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- 4 Altman DG. Randomisation: essential for reducing bias. *BMJ* 1991;302:1481-2.
- 5 Meade TW, Dyer S, Browne W, Towsend J, Frank AO. Low back pain of mechanical origin: randomised comparison of chiropractic and hospital outpatient treatment. *BMJ* 1990;300:1431-7.
- 6 Assendelft WJJ, Bouter LM, Kessels AGH. Effectiveness of chiropractic and physiotherapy in the treatment of low back pain—a critical discussion of the British randomized clinical trial. *J Manipulative Physiol Ther* 1991;14:281-6.
- 7 Koes BW, Bouter LM, Mameren van H, Essers AHM, Verstegen GMJR, Hofhuizen DM, *et al*. Randomised clinical trial of manual therapy and physiotherapy for persistent back and neck complaints: results of one year follow up. *BMJ* (in press).

Glasgow coma scale and gag reflex

SIR.—With regard to A J Stanners's comments¹ on our paper on the relation between the Glasgow coma scale and the gag reflex,² the importance of other reflexes and mechanisms in protecting the airway is beyond dispute. The paper that we originally submitted to the *BMJ* discussed these more fully and included data on the cough reflex in the patients, which showed that the cough reflex was much less easily suppressed than the gag reflex.

The cough and swallow reflexes and other protective mechanisms are not, however, easy to

assess objectively, especially in an accident and emergency department, where sophisticated assessments such as speech therapy or video-fluoroscopy are unobtainable. Also, the conditions causing acute global cerebral depression that we described are not totally analogous to the more focal or chronic conditions referred to by Stanners, and some of the above reflexes may be attenuated in elderly or debilitated patients.

Though agreeing that a normal gag reflex does not necessarily indicate a safe airway, we think that the surprising feature of our data was the absence of the gag reflex in a group of fully conscious patients who would not normally be considered to be at any appreciable risk. We thus stand by our original assertion that in accident and emergency departments the gag reflex should be assessed independently of conscious level and used as an indicator of an airway at risk.

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- 1 Stanners AJ. Glasgow coma scale and gag reflex. *BMJ* 1991;303:1401. (30 November.)
- 2 Moulton C, Pennycook A, Makower R. Relation between Glasgow coma scale and the gag reflex. *BMJ* 1991;303:1240-1. (16 November.)

SIR.—A J Stanners would rely on videofluoroscopy in diagnosing aspiration in neurologically impaired patients.¹ This cumbersome investigation has largely been superseded in our hospital by direct observation of the larynx with a flexible fiberoptic nasendoscope while a bolus of milk is swallowed. "Milk nasendoscopy" is a quick and easy investigation that can be performed at the patient's bedside if required, with equipment and expertise that should be readily available in an ear, nose, and throat department. The patient is not irradiated, and the test can be repeated as often as required.

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- 1 Stanners AJ. Glasgow coma scale and gag reflex. *BMJ* 1991;303:1401. (30 November.)

Chorionic villus sampling

SIR.—As chairman of the Medical Research Council's working party on the evaluation of chorionic villus sampling and coordinator of its European trial of chorionic villus sampling and amniocentesis¹ we are writing to dissociate ourselves from D T Y Liu's assertion, made in his capacity as a member of the working party, that "participants were still on the learning curve and results will differ if the trial is repeated."²

Our report explicitly commented on the absence of any evidence that the somewhat greater rate of fetal loss attributable to chorionic villus sampling declined as the trial proceeded, as would have occurred if those performing chorionic villus sampling were still on the learning curve. Only centres satisfying specific criteria regarding their previous experience took part in the trial. Furthermore, most patients were recruited in centres with a particularly high level of interest and skill in chorionic villus sampling. Whether results would differ if the trial is repeated is thus entirely speculative. Findings from several individual centres included the rate Liu expects based on his personal experience, and there was no evidence of heterogeneity between centres. Had Liu entered patients into the trial he would more convincingly have been able to compare his results with those of others.

It is also misleading to suggest that the Medical Research Council's European trial "was not sub-