

LETTERS

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Megatrials

Sir,

There is a clear and interesting dichotomy in the responses to my critique of megatrials (July *Journal*). Clinical scientists tend to agree enthusiastically with my points concerning the limitations of this methodology, while epidemiologists, biostatisticians, public health professionals and other professional 'number-crunchers' regard the same writings as outrageous, controversial and mistaken (Letters to the editor, November *Journal*).

This dichotomy relates to a genuine divergence in approach. Clinicians tend to be interested in obtaining estimates of therapeutic effectiveness that are valid predictions of what will happen in their patients. Megatrials are not appropriate instruments for this job,¹ and meta-analyses are even worse.² By contrast, number-crunchers (and managers) tend to be interested in obtaining estimates of effectiveness with the highest possible degree of statistical precision — even when it is unclear exactly what these numbers mean in practice.

A megatrial is not primarily defined by its size, but by its methodology: this point is quite clear in the early papers that launched the megatrial methodology.³ A megatrial is a 'large' randomized therapeutic trial that employs simplification of protocol to pursue the primary goals of maximizing size through facilitated recruitment and compliance. This size brings both increased statistical power and balancing of uncontrolled confounders between allocation groups. It is the method of simplification that I have called a methodological mistake because it usually leads to poor experimental control and heterogeneous patient recruitment.⁴

In his letter, Tom Fahey does not acknowledge the crucial distinction between, on the one hand, performing technically and statistically correct randomized trials (which is a relatively straightforward logistical matter of following standard practice), and, on the other, the much more difficult 'scientific' and 'clinical' requirements that must be

satisfied for studies to be valid and applicable. I cannot understand the reluctance to admit that most randomized trials (like most published research) are useless for most clinicians — being worthless at best and misleading at worst. For instance, when the protocol conflates a variety of ancillary treatments that influence the outcome, when trial management differs from actual practice, when the study population contain diagnostically and prognostically heterogeneous subjects, or when the trial is performed on the wrong people, then the trial results will not be predictive and cannot be taken at face value.^{4,5}

Fahey's failure to make this distinction between statistics and clinical science is shown when he states that 'empirical studies have demonstrated that bias (systematic error) is greatest when inadequate randomization occurs...' and that 'poorly randomized trials yield exaggerated treatment effects of between 30% and 40% when compared with properly randomized trials.' I'm afraid 'empirical studies' cannot show anything of the kind, because the sources and magnitude of bias are not a fixed quantity but entirely depend upon the specific circumstances of each trial and on factors such as its level of experimental control and patient selection. So, the magnitude and direction of any effect of poor randomization depends upon the amount of uncontrolled bias and the nature of the 'poor randomization'. There is no conceivable reason why the sum of specific and various experimental errors should always amount to minus 35% whatever the study!

General purpose trial 'quality' checklists entirely miss the point. In evaluating a randomized trial of, say, the chemotherapy of leukaemia, there is no substitute for detailed knowledge of both chemotherapy and leukaemia. Certainly it would be most unwise to turn over the job of evaluating clinical research to teams of biostatisticians armed with checklists.²

Megatrials have an important but secondary role in clinical research. Before performing a megatrial, clinical scientists must already have done most of the hard

work in establishing the causal nature of the therapeutic effect and the major potential sources of bias and confounding. Only then can a megatrial be designed that simplifies without distortion. The valuable megatrials of the past have conformed to this pattern of science first, megatrial later — it is only the recent, managerially driven megatrial mania that has led some people to put the cart before the horse. The time is ripe to fight back and reassert that the validity and applicability of clinical measurements should never be sacrificed to statistical exactness.⁶

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References

1. Feinstein AR. An additional basic science for clinical medicine: II. The limitations of randomized trials. *Annals of Internal Medicine* 1983; **99**: 544-550.
2. Charlton BG. The uses and abuses of meta-analysis. *Family Practice* 1996; **13**: 397-401.
3. Yusuf S, Collins R, Peto R. Why do we need some large, simple randomized trials? *Statistics in Medicine* 1984; **3**: 409-420.
4. Charlton BG. Megatrials are based on a methodological mistake. *Br J Gen Pract* 1996; **46**: 429-431.
5. Horvitz RI, Singer BH, Makuch, Viscoli CM. Can treatment that is helpful on average be harmful to some patients? A study of the conflicting information-needs of clinical enquiry and drug regulation. *Journal of Clinical Epidemiology* 1996; **49**: 395-400.
6. Charlton BG. The future of clinical research: from megatrials towards methodological rigour and representative sampling. *Journal of Evaluation in Clinical Practice* 1996; **2**: 1-11.

Scoring system for throat infection

Sir,

Whilst appreciating the design and

methodological rigour of Dobbs' study (*August Journal*), we feel it is important to question the relevance of a scoring system for group A streptococcal throat infection.¹ The derived score involving the sum of 14 items would be time-consuming and must therefore have clear benefits to the busy practitioner. The limitations of the throat swab as a gold standard are described by Del Mar.² Community studies have released a high carrier rate of streptococci but only one third of carriers will experience a rise in ASOT regardless of the presence of symptoms.³ What Dobbs has done is to produce a score that predicts *presence of* rather than *infection by* group A streptococci.

The proposed benefits of the scores ability to predict a positive swab result does not withstand scrutiny. Prevention of rheumatic fever and prevention of complications are both questionable.⁴ The treatment of sore throat with antibiotics may provide a marginal benefit in early relief of symptoms but because of the higher relapse rate associated with antibiotic use there is no overall benefit in terms of a reduction in symptom burden.⁵ Given the high symptomless carrier rates, and the fact that most patients with sore throats do not present to the doctor, it seems unlikely that the use of antibiotics will materially influence streptococcal transmission in the community.³

Thus we find it hard to see what benefits the score has in routine surgeries. The score seems to predict the presence of streptococci rather than which patients (if any) may benefit from antibiotics. Our concern is that the score may be used to 'justify' continued unjustifiable antibiotic prescribing.

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References

1. Dobbs F. A scoring system for predicting group A streptococcal throat infection. *Br J Gen Pract* 1996; **46**: 461-464.

2. Del Mar C. Managing sore throat: a literature review. I. Making the diagnosis. [Review.] *Medical Journal of Australia* 1992; **57**: 572-575.
3. Valkenburg HA, Haverkorn MJ, Goslings WRO. Streptococcal pharyngitis in the general population. II. The attack rate of rheumatic fever and acute glomerulonephritis in patients not treated with penicillin. *J Infect Dis* 1971; **124**: 348-358.
4. Shvartzman P, Little PS, Williamson I. Controversies in management. Are antibiotics appropriate for sore throats. *BMJ* 1994; **309**: 1010-1012.
5. Little PS, Williamson I. Sore throat management in general practice. *Fam Pract* 1996; **31**: 317-321.

The risk of cardiovascular disease in hypertensive patients

Sir,

Fahey and Peters¹ (November *Journal*) propose that the identification of the group of patients who have the highest absolute risk of CVS events requires consideration of multiple risk factors. We believe they are wrong in supposing that their analyses establish the practical need to perform extensive risk calculations. Well-constructed trials have shown that treating hypertension does result in reduced death rates.² Using blood pressure (BP) as the main assessment variable may not optimally identify the group that will benefit most from treatment, but has the advantage of simplicity.

The crucial question is whether the benefits of assessing other risk factors justify the effort. The use of risk factors to identify individuals who will actually have CVS events is an imperfect method.³ The New Zealand guidelines allocate patients to CBS risk strata based on BP and the other risk factors. These allocations are based on Framingham data, but involve simplifications such as:

- Considering continuous risk factors as dichotomous variables
- Equal weighting for each of the major and each of the minor risk factors, and
- An arbitrary selection of 20% 10-year risk as the threshold for treatment.

These might introduce significant distortions, and thus the New Zealand guidelines cannot be considered as the gold standard. However, by showing that BP alone selects different patients from the New Zealand guidelines, Fahey and Peters argue that BP alone is an inadequate crite-

tion. It would be preferable to use the best available risk methodology, possibly calculation based on the Framingham equations themselves, as a standard against which both practical options could be compared. The authors do accept that the ultimate 'gold standard' is the power to predict actual events, and call for longitudinal studies.

Another problem with their analysis is that many of the risk factors are not independent of BP. We need to understand the extent to which blood pressure alone predicts the total risk. For unexplained reasons, their multiple logistic regression assesses the contribution of most risk factors to CVS risk, but not blood pressure itself! This seriously undermines their conclusions. Thus, we are unable to assess whether the use of the New Zealand guidelines results in a reasonable gain of predictive power.

We believe that the treatment of hypertension in the elderly on the basis of BP alone may well make practical sense. In this group, the presence of a systolic pressure at or above 160 mmHg, or a diastolic pressure at or above 90 mmHg, indicates a substantial risk of cardiovascular events even in the absence of other risk factors.⁴

When managing hypertension in the elderly, advice to improve the estimation of risk by the routine inclusion of other risk factors will complicate the task and may not result in improved clinical outcomes. A clear simple message based on the control of BP alone may be more effective.

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References

1. Fahey TP, Peters TJ. A general practice-based study examining the absolute risk of cardiovascular disease in treated hypertensive patients. *Br J Gen Pract* 1996; **46**: 655-670.
2. Mulrow CD, Cornell JA, Herrera CR, *et al*. Hypertension in the elderly; implications and generalizability of randomized trials. *JAMA* 1994; **272**: 1932-1938.
3. Rose G. Preventive strategy and general practice. *Br J Gen Pract* 1993; **43**: 138-139.
4. Larson MG. Assessment of cardiovascular risk factors in the elderly: the Framingham heart study. *Statistics in Medicine* 1995; **14**: 1745-1756.

Skill-mix in primary care

Sir,

I am writing in response to Rashid *et al*'s editorial in the November issue of the *Journal*, 'Skill-mix in primary care: sharing clinical workload and understanding professional roles.'

General practitioners in Northern Ireland have already embraced the concept of teamwork and are actively helping to prepare a new partner in primary care: the nurse practitioner.

Since January 1995, the Royal College of Nursing has organized a course leading to a BSc(Hons) in Health Studies incorporating the Nurse Practitioner Diploma. Each of the 60 students has a medical facilitator, 49 of whom are GPs, who help teach skills in history taking, physical examination and problem solving. GPs are also partners in assessment and, in recent OSCE-style examinations, adjudicated in nine out of 12 stations. This course is an example of well-developed collaboration between doctors and nurses in the lecturing, facilitating and assessment of a future generation of health care specialists who will share the skills of both professions.

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Sir,

Thank you for the excellent editorial entitled 'Skill mix in primary care: sharing clinical workload and understanding professional roles' (November *Journal*). This covered the ground concerning GPs and nurses well. I would like to add some points concerning the practice team as a whole.

The adding of a nurse practitioner to the primary care team can allow GPs to concentrate on what they do best, while allowing the nurse practitioner to concentrate on his or her strengths. This example of skill mix increases the quality of care offered to patients and can also lead to a wider range of services. However, this concept is not limited to nurse practitioners. Two years ago we introduced a health care assistant into our nursing team to take on some of the practice nurse's traditional duties.¹ We are in the process of analysing the results of this intervention. Initial findings show that practice nurses are spending more time at work in their higher-skill range. This could allow practice nurses to offer a

broader range of skills and absorb some of the GP's increasing workload.

Furthermore, skill mix is not restricted to clinical workload. Jobs at all levels have an administrative element. Increased administrative and secretarial support for GP's and nurses can increase their efficiency. However, developments of this nature and the appointment of nurse practitioners are being hampered by the government's short-sighted restrictions on practice staff budgets. These should be expanded rather than contracted in the light of increased primary care workload.

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References

1. Jeffreys LA, Clark AL, Koperski M. Practice nurses workload and consultation patterns. *Br J Gen Pract* 1995; **45**: 415-418.

Sir,

We agree with Rashid *et al*¹ that the increase in demand for an effective primary care led NHS gives the opportunity to look at the tasks, skills and roles of GPs and nurses, and to redefine or realign them. However, in our view the problems are more complex than the rather narrow analysis presented in the editorial. Our recent work² goes some way to redress the paucity of research relating to skill mix in primary care.

Gibbs³ reviewed the literature on skill mix in 1991, which highlighted that there has been little systematic evaluation of the use of nursing skills, that there is no universally accepted methodology for the measurement of nursing workload and that, in the past, health visiting and district nursing have been examined separately.⁴ The growth in numbers of practice nurses and their developing role has been reported by Atkin *et al*⁵ and Ross, Bower and Sibbald.⁶ This role development reflects the position of general practice as the driving force for change in primary care. However, until now, the lack of mandatory training and the marginalization of practice nursing have contributed to unhelpful boundaries and role demarcations. The analysis of required skill and skill-sharing must embrace all nursing disciplines in the community.

There are a number of examples of nursing team development and organization

taking place in primary care that have been initiated by, or include, a skill mix review. In the Tile Hill project,⁷ the Roy's GP managed model⁸ was developed so that the nurses from a variety of disciplines formed and functioned as a nursing provider unit. One of the results of this has been that changes in skill mix came about through nurse participation rather than being imposed by management. Other models involve devolved nurse management, usually at practice level, with one member of the team assuming the role of leader to facilitate team and role development. The lead role may be rotated and is considered to be enabling and non-hierarchical. An important aspect of these developments is autonomy as well as financial control for the nursing team. Changes in general practice proposed in the recent white paper⁹ will undoubtedly accelerate this kind of innovation.

Our recent work assessed primary care nursing workload, use of time and the views of nurses about their work and the use of their skills. The workload measures we developed and used for the project enabled us to look at the activities of all the professional nurse groups in the primary health care setting. These instruments are being used more widely and can be developed further for use in a wide range of primary care practices.

Finally, we suggest that change in working practices is always likely to create uncertainty; skill mix reviews are extremely complex and need to be planned with great care.

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References

1. Rashid A, Watts A, Lenehan C, Haslam D. Skill mix in primary care: sharing clinical workload and understanding professional roles. *Br J Gen Pract* 1996; **45**: 639-640.
2. Rink E, Ross F, Godfrey E, Roberts G. *British Journal of Community Nursing* 1996; **1**: 364-369.
3. Gibbs I, McCaughan D, Griffiths M. Skill mix in nursing: a selective review of the literature. *J Adv Nursing* 1991; **16**: 242-249.
4. Thomas E. Approaches to the appropriate measurement of workload in primary care nursing 1995. Wessex Institute of Public Health Medicine (Unpublished).
5. Atkin K, Hirst M, Lunt N, Parker G. The role of self perceived needs of nurses employed in general practice. *Journal of Advanced Nursing* 1994; **20**: 46-52.

6. Ross F, Bower P, Sibbald B. Practice nurses: characteristics, workload and training needs. *Br J Gen Pract* 1994; **44**: 15-18.
7. Reid T. Joint input. *Nursing Times* 1993; **89**: 30-32.
8. Department of Health Nursing in the Community. *Report of the working group - the Roy report*. London: HMSO, 1990.
9. Secretary of State for Health. *Choice and opportunity. Primary care: the future*. London: HMSO, 1996.

Overdose and termination of pregnancy

Sir,

Houston and Jacobson report an interesting study on the possible association between overdose and termination of pregnancy (December *Journal*).¹ I wish to comment on certain aspects of this study.

First, the study group was restricted to women aged 15-34 years. This is not in keeping with the usual reproductive age group used in studies relating to women of reproductive age, which is usually 15-49 years.² By restricting the study group to those below the age of 35 years, one is given the impression that neither termination of pregnancy nor overdose occurs in the age group above 35 years. There is nothing further from the truth. One only needs to look at the abortion figures for England and Wales³ to appreciate the fact that older women make a substantial contribution to abortion figures, and I am certain a similar situation obtains with overdose.

Inclusion of the older age group in their study population might have affected the results in a different way. In fact, a very recent unique register linkage study of the risk of suicide associated with pregnancy among women of reproductive age (15-49) showed that the risk associated with abortion was increased in all age groups.⁴

Secondly, we were not told how many of the 163 women who had undergone termination of pregnancy, if any, had a history of major psychiatric illness. Also, how many of the 15 women who had a history of both events also had a history of major psychiatric illness? It would be interesting to have these figures because an increased risk for an overdose after termination of pregnancy may indicate either common risk factors for both events or deleterious effects of termination of pregnancy on mental stability. A history of major psychiatric illness may be a major factor in the occurrence of both events in a single individual.

Thirdly, it is interesting to theorize that

those who take an overdose are more likely to have terminations of pregnancy and vice versa, but despite the study showing a significant association between the two events, a cause and effect relationship cannot be ascribed to either. If interventions to reduce the incidence of both events are to be undertaken, we need to know where to direct scarce resources for maximum benefit. I agree with the authors that this is an area that needs further research in a larger population.

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References

1. Houston H, Jacobson L. Overdose and termination of pregnancy: an important association? *Br J Gen Pract* 1996; **46**: 737-738.
2. Fathalla M, Rosenfield A, Indriso C, et al (eds). *The FIGO manual of human reproduction. Volume 3: Reproductive Health Issues*. Carnforth: Parthenon, 1991.
3. OPCS Monitor AB95/8. HMSO: London, 1995.
4. Gissler M, Hemminki E, Lonnqvist J. Suicides after pregnancy in Finland, 1987-1994: register linkage study. *BMJ* 1996; **313**: 1431-1434.

Career preferences of medical students: some further answers

Sir,

The survey of career preferences of medical students and their exposure to general practice by Jillian Morrison and Stuart Murray (December *Journal*),¹ and the associated editorial by Professor Morrissy² omit two important variables in the influences on medical students; the attitudes of consultants, and eventual financial reward.

Despite real and perceived changes in the balance of power between primary and secondary care, there remains a belief that general practice is a lesser specialty. Teaching in hospitals at both undergraduate and postgraduate level is focused on the secondary care perspective, a distortion that remains until the end of hospital-based training for general practice at senior house officer level.³ Responsibility

for teaching falls on consultants who may feel ill-equipped to teach, as opportunities to acquire educational skills are limited.^{4,5} Conflicts between teaching, clinical workload, research and management, together with the sometimes expressed perception that consultants are not specifically paid to teach, often makes education a low priority.

Negative attitudes towards primary care are supported by differentials in eventual income, and consequent judgements may be made by undergraduates, rightly or wrongly, on the relative value of the roles. See, for example, in the discussion about salaried employment for GPs, the opinion expressed by the deputy chairman of the BMA Central Consultants and Specialists Committee that the salary scale of a GP should be that of the associate specialist grade, ranging from £22545 to £33615.

It is not yet always appreciated that a capable generalist in primary care, assessing and investigating patients and referring them when necessary to the appropriate 'partialist' in secondary care, is seen as the model for the future in many countries. In the United States, salary scales, as well as vocation, drive career choices.⁶ I understand that in some states the incomes of primary care physicians now exceed those of some cardiovascular surgeons (Professor D Onion, personal communication).

With the enthusiasm and experience of GPs who are educationally trained, education from a primary care perspective will best be served by having the undergraduates based in primary care and travelling into secondary care areas where appropriate for their clinical education.

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References

1. Morrison JM, Murray TS. Career preferences of medical students: influence of a new four-week attachment in general practice. *Br J Gen Pract* 1996; **46**: 721-725.
2. Morrissy JR. Career preferences of medical students: some unanswered questions. *Br J Gen Pract* 1996; **46**: 703-704.
3. Standing Committee on Postgraduate Medical Education. *Formal Opportunities in Postgraduate Education for Hospital Doctors in Training*. London: SCOPME, 1992.
4. Lowry S. *Medical Education*. London: BMJ Publishing Group, 1993.
5. Finucane P, Allery LA, Hayes TM. Teachers at a British medical school. *Medical Teacher* 1992; **14**: 275-282.
6. Livesy B, Davies J. The truth behind a

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7. Levinsky NG. Recruiting for primary care. *New England Journal of Medicine* 1993; **328**: 656-660.

Repeat prescribing

Sir,

We do not understand the three comments made by Dr Thornton in his letter (January *Journal*) on our paper about the scale of repeat prescribing (November *Journal*). First, we were not concerned with the savings that might be made from 'better repeat prescribing. We do not

believe that every study in general practice has to relate to costs: dragging them in here would carry our work sideways rather than forward. Secondly, he says that we should be cautious in extrapolating results from the data of 115 possible atypical practices. We think that we were cautious, since we modestly claimed only that we were offering the best data available. The widely publicized figures in the report of the National Audit Office, in contrast, came from an unpublished study carried out in just two practices.

Finally, he observes that repeats in the Meditel system may include prescriptions

that have not been issued for years. Our definition specifically excluded such items.

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