

Clinical guidelines

R31
P65
71
SCI

Clinical guidelines: development, implementation, and effectiveness

CWR Onion, T Walley

Provision of medical advice

- clinical guidelines
- protocols
- recommendations
- policies

Clinical guidelines

- Aims
- to produce the best consistent medical practice
 - based on scientific evidence or a consensus of medical opinion
 - limit use of medical resources?

Clinical guidelines

- Methods of production
- explicit approach
 - consensus conference/working party
 - synthetic method
 - health economics

Introduction

The standard of medical service provision all over the world is being increasingly questioned from within and without the medical profession. Medical scientific opinions often appear contradictory.¹ The variation in medical practice is increasingly causing concern.² Medical litigation is increasing,³ while audit is exposing sub-optimal practice. Medical knowledge is expanding so fast that doctors find it increasingly difficult to keep up-to-date. The cost of medical care is spiralling, prompting government or purchaser attempts at cost containment, or at least to ensure that limited resources are used to best effect.

To try to address these concerns, various means of providing advice on best practice to doctors have been developed (box). The forms of advice may differ, but the content is virtually synonymous; nevertheless some forms seem to have become tainted. Neither 'guideline' nor 'protocol' implies instruction or compulsion (JH Marshall, Oxford English Dictionary Word and Language Service, personal communication), but doctors commonly perceive 'protocols' as threatening and restrictive.⁴ 'Recommendation' sounds well-meaning, but lacks conviction. 'Policies' have a history of being incorporated into doctors' contractual obligations. For these reasons 'guideline' is increasingly the preferred term. In principle, there is nothing new in clinical guidelines, which have existed since the Hippocratic aphorisms.

Aims of guidelines

The aims of guidelines may seem clear (see box). In practice, one of the barriers to acceptance of guidelines has been a degree of suspicion about the underlying motivation. Is the aim of the producer to improve medical practice (as might be thought of a professional medical body) or to contain cost (as might be thought of a health authority or insurance company)? This was clearly seen in an American study of the attitudes to guidelines, in which those produced by professional groups were seen as credible, whereas those produced by an insurance company were seen as strongly influenced by financial goals – even when the guidelines were in fact the same.⁵ Similarly, guidelines produced by or sponsored by pharmaceutical companies are often viewed with suspicion, regardless of their quality. For a health authority or government, working within a fixed budget and required to make most efficient use of their limited resources, the distinction between improving quality and cost containment can become blurred. Doctors who reject the notion that costs are a valid concern in delivering health care are increasingly finding this position untenable. There is a widely held belief that development of guidelines will optimise medical therapy and increase rather than decrease costs.⁶ These beliefs remain to be substantiated.

Methods of producing guidelines

There are various methods of producing a guideline (see box). Eddy⁷ describes a systematic *explicit* approach with a thorough review of the published literature (graded according to its scientific validity), a health economic analysis, and a subsequent ranking of the possible options. A group of elite doctors then choose their preferred option; where there is no clear 'winner', the patient's preference is taken into account. Despite the scientific merit of this method, and its clear and explicit product, evidence for its effectiveness in producing changes in clinical behaviour (in the absence of financial penalties) is weak.⁸

Another approach is the consensus conference or working party. A group of well-informed experts gather together and debate the issues until a consensus is achieved. The approach is like the explicit method in reverse: the contributors present their own preference first and then use the scientific evidence to support

Wirral Health, St Catherine's Hospital,
Birkenhead L42 0LQ, UK
CWR Onion

Department of Pharmacology and
Therapeutics, University of Liverpool,
Liverpool L69 3BX, UK
T Walley

Correspondence to Prof Walley

Accepted 14 October 1994

it. To achieve consensus, it is often necessary to accommodate several preferences in the final guidelines and so the final product is often less restrictive, but more complex. Again the effectiveness of this method in producing change in actual clinical behaviour appears to be weak.⁹

Haines and Hurwitz recommend a *synthetic* method of developing local clinical guidelines, and this is now widespread in Britain.¹⁰ For each topic, a working party composed of one specialist and one general medical practitioner is commissioned. They prepare a draft which is refined by an editorial panel, whose role is to ensure consistency of style, that the guideline is understandable and can be used by nonspecialists, and that it represents a reasonably broad body of opinion. This draft is circulated for comment around all the local doctors and a final draft is published after consideration of all the comments received. In our area, we have augmented this method by holding postgraduate educational events where doctors engage in vigorous discussion of the draft. The refined guideline is then sent by post to all local practitioners, and its implementation is supported by health authority prescribing advisers in their contacts with doctors and by audit groups. This method seems initially successful, with audit showing persistent changes in prescribing behaviour towards the guideline recommendations. An example of such a guideline and the audit data pertaining to it is given in figures 1 and 2. A more rigorous evaluation of the process is currently underway.

As well as scientific evidence, health economics are often also taken into consideration in establishing guidelines. Health economics as a discipline has much to offer in the evaluation of medical interventions and should be a part of the guideline process, since often one of their aims is to achieve the greatest benefit from the available resources. But an over-reliance on health economic analysis would be inappropriate: the tools of health economics need further refinement. The results of health economic evaluation should be used as guidance to help us make better informed decisions, and not as the conclusion itself; medical practice embraces substantially more than economic efficiency.

Advantages and disadvantages of guidelines

However produced, most guidelines are a useful synthesis of the current evidence, and provide the busy clinician with up-to-date information, supported by the considered opinion of a group of responsible doctors. A doctor should easily be able to defend himself against alleged negligence arising from compliance with such guidelines. Does this imply that a doctor acting outside such agreed guidelines is open to claims of negligence? If so, this would be a major disincentive to developing guidelines; there are often many reasonable ways of managing a condition, and doctors must tailor their approach to the individual patient. Restrictive guidelines would therefore be inappropriate, and this is recognised in British law, which does not require absolute conformity in a doctor, merely that he should adopt practices that a professional man of ordinary skill would have taken when acting with ordinary care. Some think that this legal standard may change as guidelines become more fashionable.¹¹

A further hazard of guidelines is that they may establish medical practice unduly firmly and inhibit research or innovation. This again would be wrong since medical science moves on, and this must be recognised in establishing guidelines. For instance, the British Thoracic Society guidelines for the management of asthma¹² acknowledge the weaknesses of the supporting evidence, paving the way for later refinement or alteration of these guidelines.

Clinical guidelines could be viewed as a threat to clinical freedom. This may upset some doctors, but clinical freedom has been denounced as an illusion used to protect professional advantages and power, and to perpetuate ineffective (and therefore ultimately unethical) clinical practice by health economists¹³ and farsighted clinicians ('... at best a cloak for ignorance, at worst an excuse for quackery ... a myth that prevented true advance').¹⁴ While this may be an exaggeration, few would deny that there is some truth in these criticisms. A balance between clinical licence and responsibility must be achieved, and guidelines may assist in this, acting as 'beacons in the vast scientific unknown'.¹⁵

Perception of guidelines by intended users

How then are guidelines perceived by their intended users? The Nederlands Huisartsen Genootschap (Dutch College of General Practitioners) which sets national clinical guidelines for Holland found in a national survey of general practitioners in 1990 that 80% of respondents were in favour of national clinical guidelines.¹⁶ In a survey of members of the American College of Physicians, 65% of respondents thought that guidelines would improve the quality of health care, but 68% felt that guidelines might be used to discipline doctors.⁵ Younger

Clinical guidelines

Disadvantages?

- claims of negligence
- inhibit innovation or research
- threat to clinical freedom

doctors and those working in a salaried service and not in private practice had more favourable views.

There has been no national survey of this kind in the UK. We sent a questionnaire to 90 local general practitioners in 1991; 78 responded, of whom 60% said that guidelines made them feel safer, and 59% that they used current guidelines. While 72% intended to make more use of guidelines in the future, 86% thought that the effect of guidelines on medical practice was beneficial.

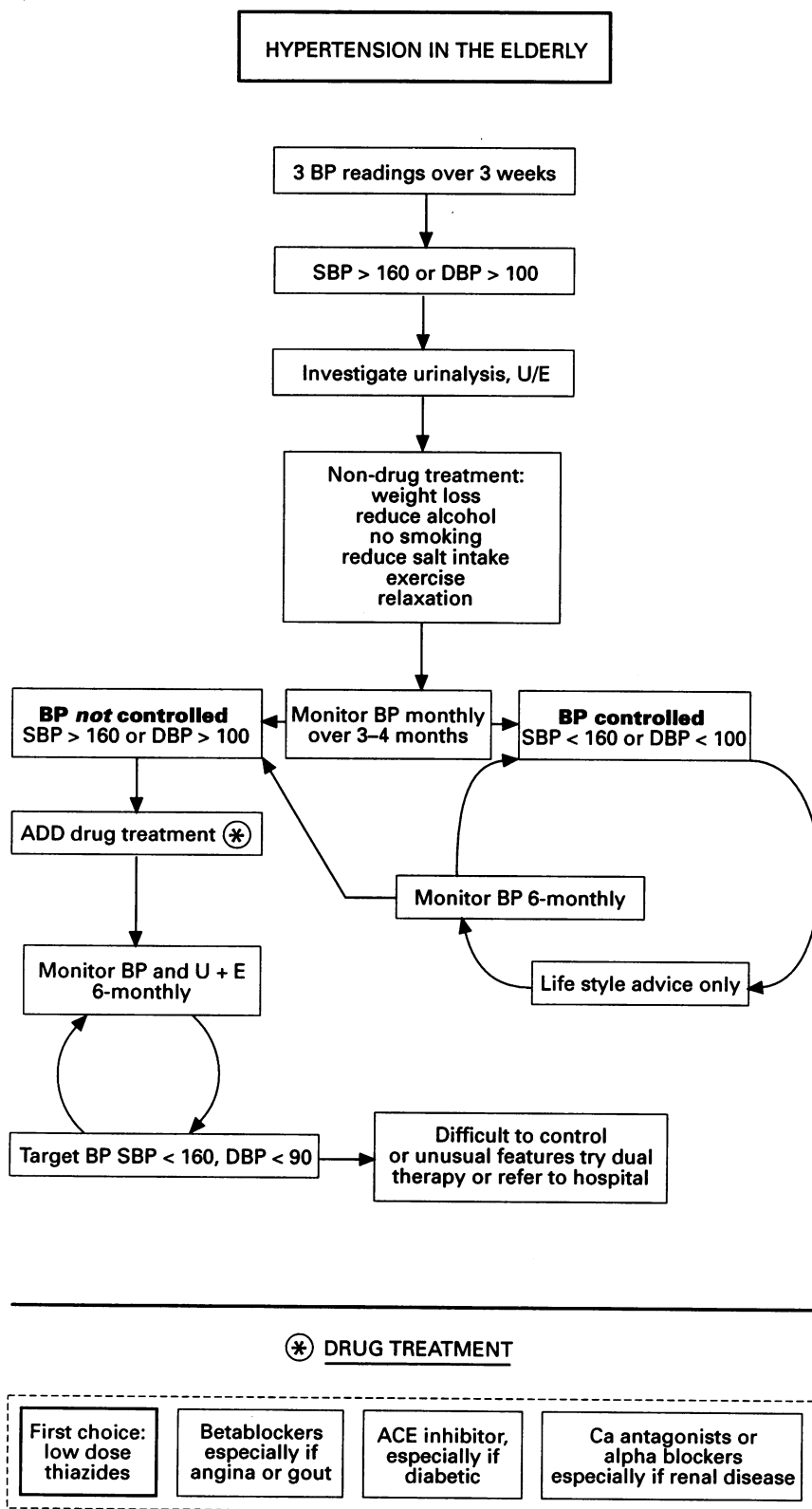


Figure 1 Local guideline for treatment of hypertension in the elderly (the reverse side contained supporting text). SBP, systolic blood pressure, DBP, diastolic blood pressure. © 1992 Wirral Health Authorities

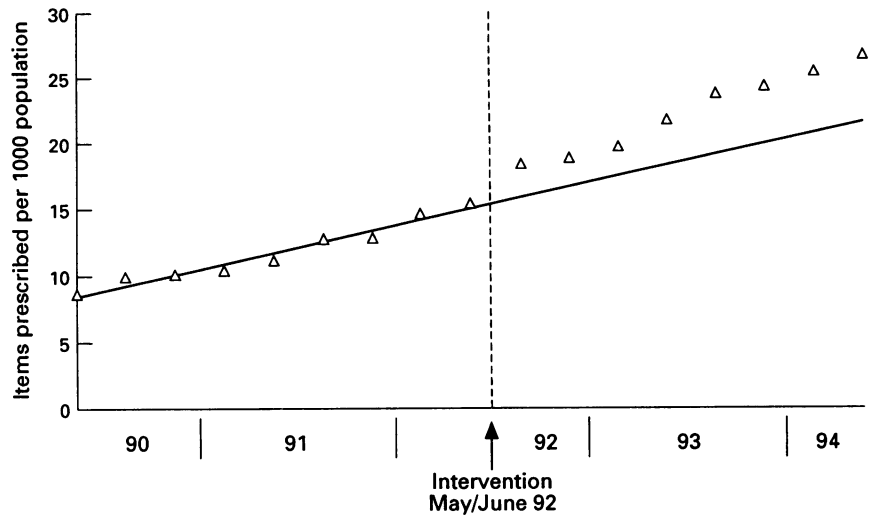


Figure 2 Effects of the hypertension guidelines on prescribing of the preferred drug option. The unbroken line is the trend line pre-protocol

It seems that the majority of the profession is convinced that guidelines are good for medicine. But what is the effect of guidelines on medical practice?

Effectiveness of guidelines

Although guidelines may be highly regarded by doctors, this may not equate with implementation; in the Dutch study, although 84% of doctors agreed with standards for diabetic care, only 44% claimed to practice to this standard.¹⁶

In a systematic review of the evaluation of clinical guidelines, all but four of the 59 studies considered showed that guidelines improved clinical care.⁶ The details of these studies are important: many incorporated feedback to users or repetition, potent compliance devices.¹⁵ Feedback is an expensive process and responses to it can become complex over time, and even the reverse of that expected may result.¹⁸ Repetition increases compliance up to a point, but may then actually cause wilful non-compliance.¹⁷ Both these features are therefore short-term aids, and are not likely to be the key to ensuring longer term changes in clinical behaviour.

There are lessons for the development of effective guidelines from the extensive experience of the development of prescribing formularies, which are essentially guidelines on rational drug use. It has been demonstrated that formularies significantly change the prescribing behaviour in a number of general practices.¹⁹ It was then thought that the distribution of well-constructed formularies would improve other practitioners' prescribing. However this has not been found; an extensive study in Northern Ireland demonstrated no correlation between formulary possession and the range or cost of drugs prescribed by practitioners.²⁰

The key element, initially missed, was that the users of the formulary in the first study were deeply involved in its production, but there was no such involvement in the second. The perception has arisen that externally imposed formularies are unlikely to affect prescribing, but personally developed formularies will; the value of such formularies lies at least in part in the self education involved.

Must the user be involved in the actual development? If this were the case then all formularies or guidelines would have to be developed locally, entailing much re-inventing of wheels – a most demoralising prospect, considering the effort required to produce a guideline. An interesting study in 1985 involved a group of young general practitioners in a deep discussion about the content of a local drug formulary. None of them had been involved in the development of the formulary, not did any of them even own a copy. Surprisingly, their compliance with the formulary (in terms of the range of drugs prescribed) rose from 73% before the discussion to 83% six months after.²¹ It appears that either involvement in the development of a formulary, or involvement in a rigorous debate about it, can influence subsequent behaviour.

Grimshaw and Russell drew up a table of the features of successful guidelines (table).⁶ Guidelines in whose development the users had a large degree of involvement ('internal'), seem to be more likely to be implemented, in contrast to nationally developed but external guidelines. Guidelines supported by specific

Table Features and effectiveness of guidelines

<i>Probability of being effective</i>	<i>Development strategy</i>	<i>Dissemination strategy</i>	<i>Implementation strategy</i>
High	Internal	Specific educational intervention	Patient specific reminder at the time of consultation
Above average	Intermediate	Continuing education	Patient specific feedback
Below average	External, local	Mailing targeted groups	General feedback
Low	External, national	Publication in journal	General reminder

From Grimshaw and Russell⁶ 1993 © *The Lancet* Ltd, with permission.

educational initiatives were more successful than those published in even the best peer-reviewed journals. Furthermore, reminding the doctor of the guidelines at the time he saw the patient improved compliance. Personal involvement and a degree of ownership of the guidelines is therefore important, but we must consider why this is so. Evaluation of the merit of the relevant evidence in the development of a guideline requires deep thinking, as does rigorous intellectual discussion about the content and validity of a completed guideline. Educationalists call this type of thinking 'deep processing' and it is well established that it is associated with a significantly enhanced understanding of the issue under scrutiny, together with improved recall of the information.²² This process seems to underlie the experience with successful implementation of formularies, and could also be applied to guidelines.

Acceptability of guidelines

Most guidelines of national or international significance are disseminated through medical journals. This alone is no guarantee of success. To encourage compliance, rewards or punishment are sometimes attached; for instance through incorporation into contracts between health care purchasers and providers.²³ These *extrinsic* methods of motivation tend only to have a short-term effect and are not associated with a deep sense of commitment amongst the intended users. *Intrinsic* motivation is much more compelling, as we have discussed above, and can be achieved through educational or organisational processes that align the aims of guidelines with the personal goals of the intended users.²⁴ Doctors, who want to provide the highest quality treatment for their patients, are unlikely to be enthused by guidelines which are seen to promote the cheapest drugs on cost grounds alone. If, however, a guideline is primarily concerned with clinical effectiveness and one of the most effective drugs is also one of the cheapest, then doctors are likely to adopt that drug with enthusiasm.

The plethora of clinical guidelines currently available have developed in a piecemeal fashion. Apart from inconsistency in style, other features of disharmony may arise. Guidelines addressing the same subject from different sources may be in part contradictory, causing confusion. This has been highlighted in the case of guidelines for the treatment of mild hypertension, where levels of blood pressure recommended for treatment or initial choice of drug have varied.²⁵ Each of these guidelines is defensible, and differences reflect the art of medicine and national attitudes more than differences in the scientific base. The experiences and working environments of the authors of guidelines may differ in many ways from those of the intended users. This can lead to the promotion of impractical guidance to practitioners, with consequent loss of faith in the guidelines. This is an argument for strong local involvement in refining even national guidelines: this approach has recently been endorsed by the UK Department of Health.²⁶ Furthermore, guidelines need to be updated regularly to incorporate medical advances and also everyday practical experience, which could significantly enhance future guidelines. The value of the views of the users of a guideline has often not been recognised. Perhaps some means of soliciting and collecting users' views should be incorporated in the revision mechanism of guidelines. As well as 'involving' the users in the process, it would ensure that any impracticalities were quickly identified and corrected.

The success of guidelines

When clinical guidelines are evaluated, it is often the compliance of doctors with the guidance that is judged the principal mark of success. Guidelines, if explicit,

Aspects of successful clinical guideline development

- detailed analysis of evidence
- holistic approach
- synthesis of specialist and generalist knowledge and experience
- involvement of users in processing of guideline content
- alignment with the professional goals of users
- criticism invited and welcomed
- revision compelled by scientific advances or criticisms from users
- multi-disciplinary approach
- clarity and simplicity in final form
- evaluation by clinical audit, preferably of patient outcomes

Recommendations for successful guidelines

- clear, simple and explicit messages
- multi-disciplinary approach to development
- improve quality rather than cost of medical care
- developed as part of an effective implementation strategy

establish clear standards against which to perform clinical audit and compliance can readily be established by comparing actual practice with that recommended. An under-investigated aspect of clinical guidelines is their effectiveness in terms of patient outcome. It is assumed that, because the content is based upon firm scientific evidence and considered opinion, improved patient outcomes must follow. This may be false, since the evidence on which guidelines, especially those produced by consensus approach, are based may be weak. Scientific trials of clinical guidelines should be encouraged, and should include an audit of patient outcomes. In this, guidelines should be treated like any other form of health technology in need of assessment.

The future

An acceleration in guideline production is now taking place and this seems appropriate. Research is more easily accessible than ever before, thanks to modern information technology, but doctors are in danger of information overload which can lead to poor practice. Information technology lends itself to these developments. Advances in electronic communication mean that guidelines could be developed internationally in very little time. Guidelines can be built into computers which are increasingly part of everyday medical practice, so assisting compliance. In the future, artificial intelligence, in the form of rule-based computer systems, may be even capable of using clinical guidelines to handle the routine decisions in clinical practice, thereby freeing the doctor to spend more time with the patient, and to solve more difficult and complex problems. It is of vital importance that if these developments occur, we do not fall into the trap of forgetting that we are dealing with individual patients to whom a guideline may not apply.

A major investment in clinical guidelines is required to coordinate and disseminate work being conducted locally, nationally and internationally.²⁷ A specific unit to address these issues could act as a resource for developing guidelines, along with an effective implementation strategy. Other responsibilities of such a unit would be to audit the success of the guidelines, both in terms of uptake and of improvement in patient outcome. By advocating the principles outlined above (summarised in the top box), such a unit could play a major role in improving patient care.

Conclusions

Clinical guidelines seem to be beneficial to medical practice and this is recognised by the majority of doctors. If they are to be of use to busy clinicians, they should be clear, simple and explicit. A multi-disciplinary approach to development, including health economic analysis, will result in greater validity. A synthesis of expert specialist, and practical generalist opinion in the development phase will ensure that the content is both scientifically valid and applicable in practice. The projected users must be involved in thinking about the issues, either by being involved in their development or through an educational approach which requires thoughtful discussion about the finished product. Guideline editors must ensure that revised editions are produced not only in response to new scientific evidence, but also in response to criticisms from users. Guidelines will receive a more sympathetic welcome from clinicians if they are intended to improve the quality of medicine, rather than purely financial efficiency or administrative convenience. A more coherent provision of health care will result if an holistic perspective is incorporated in their development. A better coordinated approach to the development of guidelines would avoid waste of resources by producing relevant guidelines with an effective implementation strategy.

1 Davey Smith G, Pekkanen J. Should there be a moratorium on the use of cholesterol lowering drugs. *BMJ* 1992; 304: 431-4.

2 Jenkins D. Investigations: how to get from guidelines to protocols. *BMJ* 1991; 303: 323-4.

3 Mann RD, Havard J, eds. *No fault compensation in medicine*. London: Royal Society of Medicine Services Ltd, 1989.

4 Hart O. Protocols or guidelines, or neither? *BMJ* 1993; 306: 816.

5 Tunis SR, Hayward RSA, Wilson MC, et al. Internists' attitudes about clinical practice guidelines. *Ann Intern Med* 1994; 120: 956-63.

6 Grimshaw JM, Russell IT. Effect of clinical guidelines on medical practice: a systematic review of rigorous evaluations. *Lancet* 1993; 342: 1317-22.

7 Eddy DM. A manual for assessing health practices and designing practice policies: the explicit approach. Philadelphia: American College of Physicians, 1992.

8 Linsk JA. Clinical design making: theory vs practice. (Letter) *JAMA* 1990; 264: 1533.

9 Russell I, Grimshaw J. In: Roland M, Coulter S, eds. *Hospital referrals*. Oxford: Oxford University Press, 1992, pp 179-211.

10 Haines A, Hurwitz B. Clinical guidelines: report of a local initiative. *Occasional paper 58*. London: Royal College of General Practitioners, 1992.

11 Anonymous. *General Practitioner* 12 March 1993, 44-5.

- 12 British Thoracic Society. Guidelines for the management of asthma; a summary. *BMJ* 1993; **306**: 776–82.
- 13 Culyer A. The promise of a reformed NHS: an economist's angle. *BMJ* 1991; **302**: 1253–6.
- 14 Hampton JR. The end of clinical freedom. *BMJ* 1983; **287**: 1237–8.
- 15 Dans P. Credibility, cookbook medicine and common sense: guidelines and the college. *Ann Intern Med* 1994; **120**: 966–8.
- 16 Grol R. National standard setting for quality of care in general practice: attitudes of general practitioners and a response to a set of stands. *Br J Gen Pract* 1990; **40**: 361–4.
- 17 Zimbardo PG, Leippe MR. *The psychology of attitude change and social influence*. New York: McGraw Hill, 1991.
- 18 Dickson D, Saunders C, Stringer M. *Rewarding people: the skill of responding positively*. London: Routledge 1993.
- 19 Green PE. The general practice formulary: its role in rational therapeutics. *JR Coll Gen Pract* 1985; **35**: 570–2.
- 20 McCarthy M, Wilson-Davis K, McGavock H. Relationship between the number of partners in a general practice and the number of different drugs prescribed by that practice. *Br J Gen Pract* 1992; **42**: 10–2.
- 21 Van Zwanenberg TD, Grant GB, Gregory DA. Can rational prescribing be assessed? *JR Coll Gen Pract* 1987; **37**: 308–10.
- 22 Newble DI, Entwistle NJ. Learning styles and approaches: implications for medical education. *Med Educ* 1986; **20**: 162–75.
- 23 NHS Executive. Winyard GPA. *Improving clinical effectiveness*. EL(93)115. Leeds; 21 December 1993.
- 24 Ford ME. *Motivating humans: goals, emotions, and personal agency beliefs*. London: Sage, 1992.
- 25 Feder G. Which guidelines to follow? *BMJ* 1994; **308**: 470–1.
- 26 NHS Executive *Improving the effectiveness of the NHS*. EL (94)74, Leeds: 28 September 1994.
- 27 Haines A, Feder G. Guidance on guidelines *BMJ* 1992; **305**: 785–6.