## Criteria for acceptability of the information provided

Key question—is the information needed for guideline appraisal provided?

- · Are the inclusion and exclusion criteria transparent, and is their rationale stated explicitly?
- Is this information accessible to all key stakeholders in written and understandable form?
- · Are the inclusion or exclusion criteria discussed and justified with reference to:

Medical criteria?

Costs and opportunity costs?

Non-medical criteria such as age, productivity, social

· Are the reasons for exclusion and inclusion stated in a form that can be recognised as valid and relevant?

non-medical characteristics of patients such as age, productivity, social status, or gender.

### Universal validity

The final criterion recognises the value of impartiality. It asks whether the reasons for exclusion are stated in a form that can be recognised by all as valid and relevant. This fundamental test is based on the close relation between impartiality and publicity.<sup>23</sup> <sup>24</sup> The requirements of publicity impose a special form on arguments. For example, arguments that are strictly self serving will not pass the test of publicity. Other reasons for exclusion, such as those based on race, religion, or sexual orientation, cannot be accepted as valid and relevant.

"Economic or political decisions should not be disguised as clinical decisions"

# Conclusion

I have discussed clinical practice guidelines as a mechanism for rationing (withholding of potentially beneficial treatment) and as a potential tool for improving the quality of decisions about rationing. If guidelines are developed through a fair process-and the public views this process as legitimate—the decisions based on guidelines are likely to be acceptable. However, the criteria for developing evidence based guidelines do not recognise explicitly the fact that guidelines might become powerful rationing tools, and additional criteria that translate deliberative democratic theory into medical practice are needed. Clinical decisions should be based on the best available evidence within the twin constraints of resource scarcity and public scrutiny.

Competing interests: None declared.

- 1  $\,$  Entwistle VA, Watt IS, Bradbury R, Pehl U. Media coverage of the Child B case. BMJ 1996;312:1587-91.
- New B, Rationing Agenda Group. The rationing agenda in the NHS. BMJ 1996:312:1593-601.
- Sackett DL, Richardson WS, Rosenberg W, Haynes RB. Evidence-based medicine. How to practice and teach EBM. Edinburgh: Churchill Livingstone,
- Eddy DM. Clinical decision making: from theory to practice. Designing a practice policy. Standards, guidelines, and options. JAMA 1990;263:3077,
- 5001, 3003. Eddy DM. Clinical decision making: from theory to practice. Guidelines for policy statements: the explicit approach. *JAMA* 1990;263:2239-40,
- Grimshaw JM, Hutchinson A. Clinical practice guidelines—do they enhance value for money in health care? *Br Med Bull* 1995;51:927-40.
- Naylor CD. Grey zones of clinical practice: some limits to evidence-based medicine. *Lancet* 1995;345:840-2.

- Klein R. Dimensions of rationing: who should do what? BMJ 1993;307:309-11.
- Gutman A, Thompson D. Democracy and disagreement. Cambridge, MA: Belknap Press of Harvard University Press, 1996.
- 10 Daniels N, Sabin J. Limits to health care: fair procedures, democratic deliberation, and the legitimacy problem for insurers. *Philosoph Public* Affairs 1997;4:303-50.
  Cohen J. Deliberation and democratic legitimacy. In: Hamlin A, Pettit P,
- eds. The good polity. Normative analysis of the state. Oxford: Basil Blackwell, 1989:17-34.
- 12 Hayward RS, Wilson MC, Tunis SR, Bass EB, Guyatt G, Evidence-Based Medicine Working Group. Users' guides to the medical literature. VIII. How to use clinical practice guidelines. A. Are the recommendations valid? *JAMA* 1995;274:570-4.
- 13 Wilson MC, Hayward RS, Tunis SR, Bass EB, Guyatt G, Evidence-Based Medicine Working Group. User's guides to the medical literature. VIII. How to use clinical practice guidelines. B. What are the recommendations and will they help you in caring for your patients? JAMA 1995;274:1630-2.
- 14 Grimshaw JM, Russel IT. Effect of clinical guidelines on medical practice: a systematic review of rigorous evaluations. *Lancet* 1993;342:1317-22.
   15 Cluzeau F, Littlejohns P, Grimshaw J, Feder G. *Appraisal instrument for*
- clinical guidelines. London: St George's Hospital Medical School, 1997.
- 16 Charles C, DeMaio S. Lay participation in health care decision making: a conceptual framework. J Health Politics Policy Law 1993;18:881-904.
- 17 Pringle M, Wallis H, Fairbairn S. Involving practice staff and patients in determining standards and priorities in primary care. Eur J Gen Pract
- 18 Crisp R, Hope T, Ebbs D. The Asbury draft policy on ethical use of resources. BMJ 1996;312:1528-31. (Discussion BMJ 1996;312:1531-3.)
- 19 Ham C. Retracing the Oregon trail: the experience of rationing and the Oregon health plan. BMJ 1988;316:1965-9.
- 20 Conway T, Hu TC, Harrington T. Setting health priorities: community boards accurately reflect the preferences of the community's residents. J Commun Health 1997;22:57-68.
- 21 Redman S, Carrick S, Cockburn J, Hirst S. Consulting about priorities for the NHMRC National Breast Cancer Centre: how good is the nominal group technique. Aust NZ J Public Health 1997;21:250-6.
- 22 Lenaghan J, New B, Mitchell E. Setting priorities: is there a role for citizens' juries? BMJ 1996;312:1591-3.
  23 Rawls J. Political liberalism. New York: Columbia University Press, 1993.
- Scanlon TM. What we owe to each other. Cambridge, MA: Belknap Press of Harvard University Press, 1998.

(Accepted 12 May 1999)

# Corrections and clarifications

Benzodiazepine use in pregnancy and major malformations or oral clefts

In the first of this cluster of letters (2 October, p 918), the first author's name is Ester Garne (not Game).

Medicopolitical digest

In the third paragraph of the section "Public health must not be sidelined" (2 October, p 925) Mr Rajan Madhok should have been described as director of health policy and public health at East Riding Health Authority.

Pre-existing risk factor profiles in users and non-users of hormone replacement therapy: prospective cohort study in Gothenburg, Sweden

Two errors occurred in this paper by Kerstin Rödström and colleagues (2 October, pp 890-3). Firstly, the results section in the abstract should start: "179 of the 1201 [not 1202] women." Secondly, the final sentence of the first paragraph of the discussion should read: "Specifically, a 20 mm Hg decrease [not increase] in systolic blood pressure and a high socioeconomic background each increased the likelihood of hormone replacement therapy use by around 50%."

#### Minerva

Minerva is only human. In the seventh paragraph on p 650 of the issue of 4 September, she inadvertently omitted to cite the source journal. The study of the rate of leukaemia in the Warrawong area of New South Wales, Australia, and the accompanying comment suggesting that analysis of disease clusters rarely yields anything useful both appeared in the Medical Journal of Australia (1999;171:178-83).