

has recently been confirmed in the Nurses' Health Study,⁹ and the results of a secondary prevention study (heart and oestrogen/progestin replacement study) are expected in 1999.

Doctors and managers are understandably concerned about the cost implications of widespread use of lipid lowering treatment. However, a cost minimisation analysis of the 4S study's data concluded that the reduced use of hospital services that would result from use of simvastatin in a similar group of patients in the United States would offset most of the cost of treatment.¹⁰ Cost effectiveness of expensive drug treatments such as the statins depends on risk of ischaemic heart disease. A cost effectiveness study based on the findings of the 4S study estimated that simvastatin treatment of men aged 55-64 who have suffered a myocardial infarction would cost £6000 per life year saved, whereas it would cost £361 000 per life year saved for women aged 45-54 with angina.¹¹ Consideration of the direct costs to health services of morbidity from ischaemic heart disease or the indirect costs of mortality or morbidity to

patients, families, and society would reduce these estimates, and further economic analyses are required. In conclusion, data are now available to show that treatment with lipid lowering drugs is effective in reducing major coronary events in people with ischaemic heart disease and "normal" cholesterol concentrations. In an era of evidence based medicine this finding is likely to have major financial implications for the providers of health care.

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Allocating budgets for fundholding and prescribing

Practice based needs assessment may be the only real answer

The way in which health authorities come to their decisions about budgets for fundholding and prescribing must seem like an arcane art to many general practitioners. The principle underlying the setting of these budgets is that general practices should receive a fair share of NHS resources and one that reflects the healthcare needs of their patients.^{1,2} However, there are great practical problems in setting budgets fairly. The main problem is that attempts to explain variations in the use of fundholding procedures and in prescribing costs have not been very successful.^{3,5} The variations between practices are just too large to be explained by currently available information. The most important reason for this is that general practices serve small populations that differ greatly from each other in their demographic, social, and clinical characteristics. There are also large differences in the way in which general practitioners provide care. Hence, resource allocation formulae, such as those used by the NHS Executive to allocate budgets to health authorities, will not work well at practice level.

Despite these problems, there have been some recent developments in setting general practice budgets. For example, many health authorities are using capitation based formulae to allocate budgets to practices that are total fundholders (responsible for buying all the health services received by their patients). The budgets of these practices are large (around £4m for a practice with 10 000 patients), and health authorities, quite rightly, want to fund them fairly so that neither their patients nor the patients of other practices are disadvantaged. To help achieve this aim, some health authorities have used the new NHS Executive resource allocation formula to allocate budgets to total fundholders.^{6,7} The NHS Executive will use this formula to allocate budgets for hospital and community health services to health

authorities, and the use of this formula by health authorities to allocate budgets to total fundholders seems reasonable.

However, there are a number of problems with this approach. Firstly, the NHS Executive applied the weighting for need in the formula to only 76% of funding and not 100%. The effect of this is to reduce the resources allocated to health authorities with a high need for care.⁸ If health authorities follow the executive's example, this will result in smaller budgets for practices located in deprived areas. Secondly, the census variables used by health authorities in their calculation of practice budgets are estimates, and we do not know if these estimated values are accurate enough to be used in resource allocation formulae. Finally, routine sources of data such as the census contain only limited information on many groups with a high need for care, such as the homeless or refugees.

There have also been some developments in setting prescribing budgets. Prescribing allocations to health authorities have traditionally been based on historical spending. The NHS Executive hopes to move away from this approach and is considering the introduction of a weighted capitation formula to allocate prescribing budgets to health authorities. The NHS Executive has identified age, sex, cross boundary flows, and chronic illness as the best predictors of prescribing costs. Health authorities that were 2% below the predicted spending per person on drugs were given a slightly larger increase in their 1996-7 budget than other health authorities.² The NHS Executive has commissioned further work, and it is likely that prescribing budgets to health authorities will eventually be allocated using weighted capitation.

Although the NHS Executive is encouraging health authorities to think about using weighted capitation when they in turn allocate budgets to practices, they will find this difficult to do. Attempts to explain variations in prescribing costs between

practices have only explained about 30-40% of this variation.^{4,5} Hence, a capitation based formula would be difficult to use at practice level. Despite the problems outlined above, health authorities need to move from practice budgets based on historical spending to budgets based on the need for care of practice populations.⁹ Health authorities are making some progress in this area, but it may be several years before substantial progress is made.¹⁰

In the interim, what can be done to improve the process of setting budgets for general practices? Firstly, general practitioners should be better informed about how budgets are set, and, to facilitate this, health authorities should publish the criteria they use to set budgets. Secondly, information on budgets for fundholding and prescribing should be included in the primary care indicator packages that health authorities are developing.¹¹ This would allow general practitioners to compare the budgets of their own practices with those of other local practices. Thirdly, health authorities should use weighted capitation as a guide to setting practice budgets and not as the ultimate determinant of these budgets. Rigid, inflexible application of weighted capitation may lead to practices becoming reluctant to register patients who need high cost care.¹² For the foreseeable future, therefore, there

will continue to be some subjectivity in allocating budgets to general practices, and hence budget setting will remain an area that will generate controversy and debate.

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Cervical sampling devices

Extended tip spatulas (such as the Aylesbury) should replace the Ayre

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In 1994-5, 4.5 million cervical smears were examined in England; over 350 000 (7.9%) were deemed inadequate.¹ Inadequacy rates reported by the 183 laboratories ranged from 0.2-35.5%. Such variation is unacceptable and must in part reflect different reporting criteria. Guidelines that should lead to a greater uniformity in reporting have since been circulated.² The rates also depend, however, on the quality of smear taking, and there is room for improvement here too.

In this week's *BMJ*, Buntinx and Brouwers (p 1285) review the relation between sampling devices and detection of dyskaryosis.³ The data suggest that extended tip spatulas (such as the Aylesbury) should be used in preference to Ayre spatulas and that brushes may be beneficial when used in conjunction with spatulas but that they should not be used alone. Here I will consider the appropriateness of combining results from studies with very different designs and the appropriateness of the endpoints used to evaluate screening.

The ideal sampling device would minimise the amount of cervical cancer prevented while minimising the costs of screening. No randomised study has evaluated prevention of cervical cancer directly; all have relied on surrogate endpoints. The best surrogate is perhaps the number of women treated for (histologically confirmed) high grade cervical intraepithelial neoplasia. Even this imperfect endpoint is not available in most studies; instead they rely on the rates of cytological abnormalities detected. A device associated with a higher rate of dyskaryosis would be judged to be superior, even if it were no better at cancer prevention, despite the costs (financial and psychosocial) of additional referrals. A good surrogate endpoint must be an accurate predictor of cancer prevention. Additionally, the chances of preventing cancer given the surrogate should be the same for all sampling devices in the study.⁴ Suppose one sampling device picked up additional cases of mild dyskaryosis based on cells sampled some distance from the transformation zone. If such cases were less frequently associated with progressive disease, the surrogate would be inappropriate.

Dey *et al* recently argued that inadequacy rates could be used as a surrogate for smear quality and that smear quality

may be more appropriate than dyskaryosis for assessing cancer prevention.⁵ Although reducing the number of repeat smears would have clear cost benefits, one must be careful not to overinterpret the clinical importance of a reduced inadequacy rate. Mitchell and Medley showed that the incidence of cervical intraepithelial neoplasia in 20 000 women with a previous negative smear was not significantly different in those whose initial smear did or did not lack an endocervical component.⁶ It is now accepted that a report of "inadequate" should not depend solely on the presence or absence of endocervical cells, but it is still doubtful whether inadequacy rates can be considered a surrogate for screening efficacy.

The rates of dyskaryosis in Buntinx and Brouwers' paper range from under 1% in a screening setting to over 85% in a study of women referred with abnormal cytology.³ Combining relative risks from settings with such diverse underlying rates is hardly meaningful—a relative risk of 2 is impossible when the baseline is 80%. The use of odds ratios, while still problematic, seems more appropriate (table). The sampling device most suitable for routine screening may not be optimal for women who have been previously treated for cervical intraepithelial neoplasia. Data from the overview suggest that, whereas there is little advantage from using a brush in addition to a spatula in routine screening, the benefit in women referred with a previous abnormal smear may be more substantial (table).

Registrations of adenocarcinoma of the cervix have increased substantially in both Britain and the United States,⁷ and there is concern that cytological screening is less effective in preventing adenocarcinomas. Whereas the transformation zone must be adequately sampled for identification of precancerous squamous lesions, adenocarcinomas are likely to originate further up the endocervical canal. Thus there should be particular interest in the ability of sampling devices to pick up glandular lesions.

Testing for human papillomavirus is thought to be less reliant on adequate sampling of cervical cells, but as long as screening is based on cytology it is important for smears to be taken by trained practitioners using an appropriate device (such as an extended tip spatula), supplemented by a brush