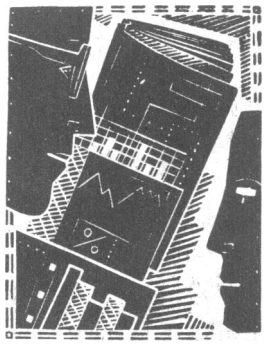

Failure to deliver hepatitis B vaccine: confessions from a genitourinary medicine clinic

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Abstract

***Objective*—To audit hepatitis B immunisation of homosexual or bisexual men in a genitourinary medicine clinic.**

***Design*—Retrospective case note review of all homosexual and bisexual men presenting to a genitourinary clinic as new patients during 12 months in 1988 and follow up review of notes to May 1990.**

***Setting*—One department of genitourinary medicine, Middlesex Hospital.**

***Patients*—758 homosexual or bisexual men, of whom 207 started a course of hepatitis B vaccine in 1988. Case notes were unavailable for one patient.**

***Main outcome measures*—The proportion of patients screened for hepatitis B virus markers, the proportion of susceptible patients immunised, the proportion completing the vaccine course, and the proportion rendered immune.**

***Results*—25 men had been previously tested for hepatitis markers; of the 732 not previously tested, 440 (60·1%) were screened for hepatitis B markers. 207 (69%) of the 300 patients without hepatitis B serological markers started the vaccine course, and 141 (68%) completed it, with 75 (84%) of the 89 tested after immunisation being immune. An estimated 24% of susceptible new patients were rendered immune as a result of the immunisation policy. Patients who presented with a further episode of a sexually transmitted disease were more likely to have been screened (25% *v* 12%, $p<0·0001$) and immunised (31% *v* 18% $p=0·02$); those known or found to be positive for HIV antibody were more likely to have been screened (23% *v* 14%, $p=0·047$) but less likely to have been immunised (6% *v* 17%, $p=0·004$).**

***Conclusions*—The major failure was that in not screening; failure to immunise patients found to be susceptible and failure of compliance with the vaccine course contributed. Non-response to the vaccine was of minor importance. Improvements in vaccine delivery are required.**

***Implications*—Other providers should be encouraged to review their performance.**

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BMJ 1991;303:97-101

Introduction

Homosexual and bisexual men attending genitourinary medicine clinics have a high prevalence of serological markers of hepatitis B virus infection. Acute or chronic current infection, determined by the presence of hepatitis B surface antigen in serum, has been found in 4-10% of such patients, and 40-70% have markers of past exposure.[1-7] In 1987, 48% of serum samples from homosexual and bisexual men attending this clinic contained evidence of past or present infection with hepatitis B virus, determined by the presence of antibody to hepatitis B virus core antigen.[8,9]

An effective plasma-derived vaccine to hepatitis B surface antigen became available in 1982 and was followed by recombinant vaccines expressed in yeast.[10-12] An analysis in the United States indicated that immunisation of homosexual men would result in a reduction in health care costs,[13] and a similar projection in the United Kingdom showed that it would also be cost effective because of a reduction in health care costs and other costs related to acute hepatitis.[14]

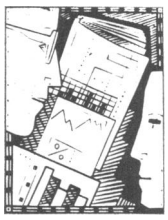
In the United States immunisation has been recommended for all homosexual men, regardless of age or duration of homosexual practices.[15] In the United Kingdom the Department of Health recommends that immunisation be considered for subjects who frequently change sexual partners, particularly those who are prostitutes or homosexual men.[16] Despite this recommendation a postal survey of genitourinary medicine clinics in the United Kingdom in 1988 showed that many did not routinely screen for hepatitis B virus infection and that only 30% offered immunisation.[17] There has been no report from a genitourinary medicine clinic of the effectiveness of an immunisation policy, where such a policy exists.

We carried out an audit of hepatitis B immunisation by reviewing the case notes of homosexual and bisexual men attending a genitourinary medicine clinic. Its aims were to determine the proportion of patients being screened for hepatitis B markers and, when shown to be susceptible, the proportion completing a course of immunisation with consequent seroconversion for antibody to hepatitis B virus surface antigen.

Patients and methods

The period of audit was the 12 months of 1988, chosen as the most recent year which allowed an adequate period for all patients starting the immunisation course to complete it. Data were collected on all patients up to May 1990. Of 235 patients who started a course of hepatitis B vaccine in 1988, 227 (97%) were homosexual or bisexual men, of whom 207 (91%) first presented to the clinic that year and were therefore new patients. Analysis was restricted to these new patients, who were compared with all 551 other homosexual or bisexual men who were new patients in 1988. The notes of all 758 patients, including those receiving vaccine were reviewed. The following data were extracted from the clinic notes: age, nationality, additional risk factors for hepatitis B infection, hepatitis B serological test results and immunisation record, tests after immunisation, any record of HIV serological tests and status, and current and past sexually transmitted diseases and number of subsequent presentations when one or more sexually transmitted disease had been diagnosed, up to May 1990.

During the study period it was the recommended practice of the clinic that homosexual or bisexual men should be offered screening for serological markers of

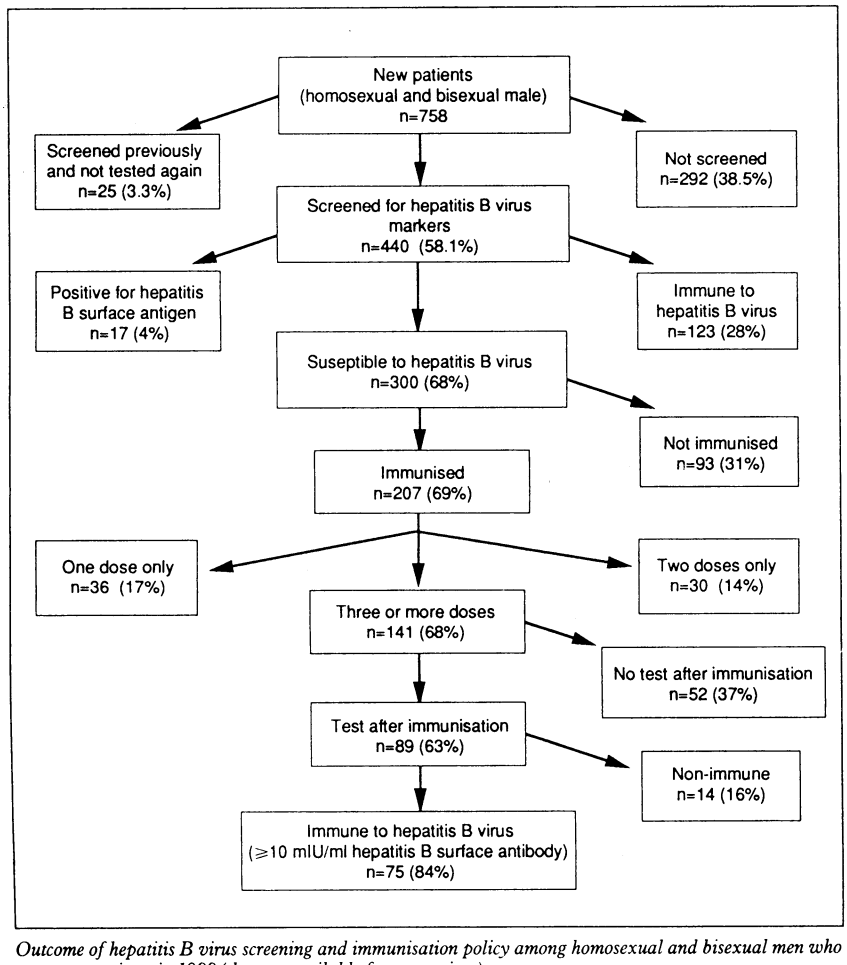


hepatitis B virus infection. The tests performed were to detect antibodies to surface and core antigens by "in house" radioimmunoassays[18] and surface antigen by enzyme immunoassay (Wellcozyme, Wellcome Diagnostics). If the subject was not immune immunisation with a recombinant yeast-derived vaccine (20 μg Engerix B, Smith Kline and French) was recommended, given by injection into the deltoid muscle in the standard three dose schedule (0, one, and six months). Repeat serological testing was advised one to two months after completing the course with quantification of surface antibody titre. At the time of their first and second doses patients were invited to self address an envelope for a reminder letter to be sent before the date of their next scheduled dose of vaccine. No further reminders for immunisation or for testing after immunisation were sent.

Comparisons were made between men screened for hepatitis B virus markers and those who were not and between those who were immunised and those who were not. Additional comparisons were made between those who completed the course of vaccine and those who received only one or two doses. The Mann-Whitney U test was used for comparisons of continuous variables. χ^2 or Fisher's exact test was used to examine the relation between dichotomous variables, and odds ratios with 95% confidence intervals were calculated.

Results

The 758 new patients reviewed had a mean age of 30 years (SD 9 years) and 634 (83·6%) were residents in the United Kingdom. At presentation a sexually transmitted disease other than hepatitis B or HIV infection was diagnosed in 222 (29·3%), and 355 (46·8%) had a history of sexually transmitted disease. HIV antibody status was determined in 307 patients at their first clinic attendance or one month afterwards, of whom 80 (26%) were positive; 32 patients were already known to be positive for HIV antibody before attending the clinic. Although not systematically sought, risk factors for hepatitis B in addition to homosexuality were identified in 28 (3·7%) patients.



Outcome of hepatitis B virus screening and immunisation policy among homosexual and bisexual men who were new patients in 1988 (data unavailable for one patient)

TABLE I—*Intervals between screening before immunisation, vaccine doses, and testing for immunity after immunisation*

First clinic attendance to hepatitis B virus test (n=435)			
Interval (weeks)	<2	2-12	>12
No (%) men	372 (86)	23 (5)	40 (9)
Test before immunisation to first vaccine dose (n=201)			
Interval (weeks)	<4	4-12	>12
No (%) men	168 (84)	19 (9)	14 (7)
First to second vaccine dose (n=163)			
Interval (weeks)	<6	6-12	>12
No (%) men	137 (84)	20 (12)	6 (4)
First to third vaccine dose (n=138)			
Interval (weeks)	<30	30-52	>52
No (%) men	116 (84)	22 (16)	
Third vaccine dose to test for immunity (n=88)			
Interval (weeks)	<8	8-24	>24
No (%) men	40 (45)	36 (41)	12 (14)

HEPATITIS B TESTING

Twenty five (3·3%) patients were recorded as having been tested previously, and for one patient no information was available. Of those previously tested, eight were immune by natural infection, 10 had been immunised, four were non-immune, and in three their immune state was uncertain. Of the 732 patients not previously tested, 440 (60·1%) were tested, most within two weeks (figure and table I). Tests for core antibody or surface antibody, or both, were positive in 140 (31·8%, 95% confidence interval 27·5 to 36·2) patients, of whom 17 (4% of those tested, 2·1 to 5·7) were positive for hepatitis B surface antigen. After excluding those patients previously tested 292 (39·9%) of the 732 patients were not tested, but for only five was it recorded that they had declined; in the remainder the reason was not recorded.

Patients tested for hepatitis B virus markers were younger than those not tested and a greater proportion had presented again to the clinic with a further sexually transmitted disease by the end of the follow up period (table II). This could have been owing to the increased opportunity for testing at subsequent visits; the difference remained, however, when only tests on or within seven days after first attendance were considered. Patients tested for HIV antibody were more likely to be tested also for hepatitis B virus markers. Similarly, patients found to be positive for HIV antibody or already known to be positive were more likely to be tested. There were no significant differences between the two groups with respect to nationality or current or previous sexually transmitted disease.

HEPATITIS B IMMUNISATION

Hepatitis B serological test results were negative in 300 (68%) of the 440 patients tested, of whom 207 (69%) started a course of vaccine. No patient was immunised without prior testing. Of the 93 (31%) patients not immunised, 40 (43%) declined, 20 (22%) failed to attend or telephone for results, 23 (25%) attended but did not receive vaccine for reasons that were not recorded, six (6%) were given their result by telephone but did not reattend, and four (4%) preferred to be immunised elsewhere. Patients receiving vaccine were more likely to present again to the clinic with a further episode of a sexually transmitted disease than those who were not immunised (table III). As with screening before immunisation this could have been confounded by the increased opportunity provided by the additional visits to the clinic. This is unlikely, however, because the interval between the date of testing for hepatitis B virus markers and the first dose

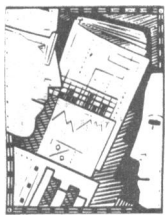


TABLE II—*Subsequent sexually transmitted disease, test for HIV antibody, and presence of HIV antibody in patients tested or not tested for hepatitis B virus markers*

	Tested	Not tested	Odds ratio (95% confidence interval)	p Value
Mean (SD) age (years)	29·6 (9·2)	31·3 (9·5)		0·002
No (%) of patients with subsequent sexually transmitted disease	109/438 (25)	36/292 (12)	2·36 (1·53 to 3·63)	<0·0001
No (%) of patients with subsequent sexually transmitted disease (including in the tested group only those tested within 7 days after first attendance)	85/356 (24)	64/400 (16)	1·65 (1·13 to 2·40)	0·007
No (%) of patients having test for HIV antibody at first attendance (excluding patients already known to be positive)	181/415 (44)	91/289 (31)	1·68 (1·21 to 2·34)	0·001
No (%) of patients already known to be positive for HIV antibody or positive on testing at first attendance	62/272 (23)	15/109 (14)	1·85 (1·00 to 3·42)	0·047

TABLE III—*Subsequent sexually transmitted disease, test for HIV antibody, and presence of HIV antibody in patients susceptible to hepatitis B virus receiving or not receiving hepatitis B vaccine*

	Immunised	Not immunised	Odds ratio (95% confidence interval)	p Value
Mean (SD) age (years)	27·2 (7·6)	29·6 (9·3)		0·07
No (%) of patients with subsequent sexually transmitted disease	64/207 (31)	16/88 (18)	2·01 (1·09 to 3·73)	0·02
No (%) of patients having test for HIV antibody	74/206 (36)	45/85 (53)	0·50 (0·30 to 0·83)	0·007
No (%) of patients positive for HIV antibody on testing	7/121 (6)	9/54 (17)	0·31 (0·11 to 0·87)	0·004*

*With Fisher's exact test.

of vaccine did not differ between those who had a further sexually transmitted disease and those who did not (p=0·35). Patients tested for HIV antibody and those found to be infected with HIV were less likely to have been immunised than those not tested or found to be negative for HIV antibody. There were no significant differences between the two groups with respect to age, nationality, diagnosis at presentation, or history of past sexually transmitted diseases.

Of the 207 patients who started a course of vaccine, 141 (68%) completed it; 36 (17%) patients received only one dose and 30 (14·5%) only two doses. Few patients had an appreciable delay between doses (table I). There was a trend towards patients completing the course being more likely to present to the clinic again with an episode of sexually transmitted disease than those not completing it (50/141 *v* 14/66, odds ratio 2·04; 0·98 to 4·29). The interval between screening before immunisation and the date of the last dose of vaccine did not differ according to the occurrence of subsequent sexually transmitted disease, and there were no other significant differences between the two groups. Testing after immunisation was performed in 89 (63%) of those who completed the course, with a hepatitis B surface antibody concentration of ≥10 mIU/ml detected in 75 (84%) patients, including two patients who had also seroconverted for core antibody due to subclinical infection.

From these data the proportion of all new patients initially susceptible to hepatitis B virus infection who were rendered immune may be estimated. After excluding the few patients already immunised and assuming that the prevalence of markers of hepatitis B infection is the same in patients regardless of testing 499 (68%) of the 732 new patients would have been susceptible to hepatitis B virus infection. Only 141 (28%) of 499 susceptible patients completed the course of vaccine, and of the 89 (63%) tested after immunisation, 75 (84%) had seroconverted for surface antibody and had a titre of antibody believed to be protective. If a uniform response rate is assumed among those completing a course of immunisation 119 patients were rendered immune, which represents only 24% of the susceptible population of 499 patients.

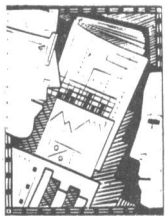
Discussion

We estimated that only about a quarter of homosexual and bisexual men presenting as new patients to a genitourinary medicine clinic and assumed to be susceptible to hepatitis B virus infection were effectively immunised by a course of a recombinant vaccine. This failure to implement the policy of the clinic may be attributed to several factors, which include failure to screen for hepatitis B virus markers, failure to give vaccine to those identified as susceptible, poor patient compliance, and non-responsiveness to the vaccine.

The major failure was in not testing about 40% of new homosexual and bisexual patients presenting to the clinic. In most cases the reason for this could not be determined by review of the case records, although a few patients had declined or had been tested elsewhere. The prevalence of core antibody of 32% among those tested and an earlier anonymous seroprevalence study[8,9] confirm that this population is at risk of hepatitis B virus infection.

The failure to test for hepatitis B virus markers was compounded by a failure to immunise those identified as susceptible, the reason for which in most cases could not be determined from a review of the case notes. Of the patients who commenced the vaccine course, about one third failed to complete it despite a system in the clinic for sending reminder letters. In most of those who did receive vaccine the intervals between testing and vaccine doses were appropriate. Together, the patients who did not complete the course were given 94 (17·3%) of the 543 doses of vaccine used, with little likelihood of benefit. The only subgroup of patients showing a trend towards being more likely to complete the course were those reattending with another episode of sexually transmitted disease. By their subsequent clinical history, this subgroup may have shown that they were at highest risk of acquiring hepatitis B virus infection. This risk may have been perceived by doctors at the initial consultation, but the factors influencing them cannot be deduced from this study.

The response rate of 84% among those tested after immunisation was low compared with that achieved in clinical trials. This may be attributable to the proportion of patients with HIV infection, in whom the response to immunisation is appreciably reduced.[19,20] This is supported by a simple calculation: assuming, from earlier data on seroprevalence,[8] an approximate HIV antibody prevalence of 25% and a vaccine response rate of 50% among the patients positive for HIV antibody and 95% among the patients negative for the antibody then the expected response rate in this population is 83·6%, similar to that observed. Although an important issue in future vaccine development, the response rate was a minor consideration



in the overall efficacy of the immunisation policy.

We showed a clear need to improve delivery of hepatitis B virus vaccine to this population. Loke *et al* showed the wide variation in policy among different genitourinary medicine clinics, although the situation may have improved since their survey was conducted.[17] In the United Kingdom there are no national guidelines for clinical practice in sexually transmitted diseases, such as are produced by the Centers for Disease Control for the United States.[21] Perhaps more specific recommendations than are provided at present[16] would improve the provision of this service and the awareness of clinicians. Despite the clear recommendations few homosexual men in the United States have been immunised.[22-24] Concerns about vaccine cost and safety and lack of health education were seen as having contributed to the failure. Improvement in the provision of the service must be linked with a programme of education of patients and other members of the public at risk. The voluntary organisations Group B and the Terrence Higgins Trust have recently launched such a programme directed at homosexual and bisexual men.

Changes in behaviour that have occurred since the onset of the HIV epidemic may have been responsible for a reduction in the attack rate of hepatitis B virus infection which has been reported.[25,26] However, HIV infection prolongs the period of infectivity of those who acquire the infection by increasing the proportion of those becoming carriers.[27] There is also a trend towards a lower rate, among carriers, of spontaneous seroconversion from being positive for hepatitis B e antigen to the less infectious negative state[28,29] and a significant reduction in the rate of loss of hepatitis B virus DNA from serum.[30] HIV infection also diminishes the immunogenicity of the vaccine. In this study patients infected with HIV were less likely to be immunised than the others tested. This may have been because they were erroneously perceived not to be at risk, or not to respond to the vaccine.

The rise in the prevalence of HIV infection and changes in sexual behaviour among homosexual men observed since the analysis of the cost effectiveness of immunisation referred to above[14] will affect that analysis. The cost effectiveness will have been reduced by the decrease in the response rate to the vaccine among patients positive for HIV antibody and the fall in attack rate but increased by the prolongation of infectivity. Additionally, the original analysis was undertaken when the cost of the vaccine was high, and it excluded the additional costs associated with the late sequelae of persistent infection.

When a policy to screen and immunise is in place an exercise in audit such as that reported here is an essential assessment of clinical performance. The study identified several failures and suggested some solutions, some of which have been implemented. These include a printed reminder of the screening and immunisation policy which has been provided for all clinicians; a checklist has been attached to the syphilis serology proforma as a further reminder. Although routine testing of all patients would increase the effectiveness of screening for hepatitis B markers, the number of unnecessary and repeat tests that would be requested would be unacceptable. Hepatitis B serological tests are therefore still performed only when a request form is completed by the doctor. The need for patients to attend for the results of tests has been emphasised in a patient information leaflet. A few patients might have been immunised if the results of hepatitis B serological testing had been available with other results at the routine one week follow up appointment. The regular reporting of all hepatitis B serological test results within this period has not yet been achieved. As an alternative to the standard 0-1-6 month immunisation schedule, a 0-1-2 month schedule has been suggested, but a booster dose is then recommended at 12 months to achieve equivalent antibody titres and presumed duration of protection.[31] Patient compliance may be improved by adopting this schedule but no such comparison has been published. A patient recall system is advisable. Our simple recall system could not be readily assessed. In future a computerised system might incorporate sufficient checks to allow an assessment of the recall system. An alternative approach would be to involve the patient's general practitioner. A few patients did opt to go to their general practitioner for immunisation, but many are not registered and others are concerned about confidentiality.

A further dimension to the issues of delivery of hepatitis B vaccine is added by the recommendation now current in the United States that immunisation should be extended to heterosexuals attending clinics for sexually transmitted diseases and reporting multiple sexual partners or with a diagnosis of sexually transmitted disease. Before such a recommendation could be endorsed in other countries, and apart from considering need and cost, the vaccine must be shown to be effectively delivered. We have exposed the poor performance achieved in this clinic in 1988; others are encouraged not to assume that they are doing better.

The help of the late Dr C H Cameron with the serological assays for hepatitis B virus is gratefully acknowledged. We thank Dr J S Bingham, Professor M W Adler, Dr A Mindel, and Dr D E Mercey, consultants in genitourinary medicine, and Dr A M Johnson for their help and advice. RJCG was supported by the clinical research and development committee of the University College and Middlesex School of Medicine.

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(Accepted 3 April 1991)

Audit in Person

When medical audit starts to count

David Bowden, Kieran Walshe

Medical audit has been the least controversial element of the NHS reforms. Its widespread acceptance by clinicians has been encouraging, though it is not surprising that organised medical audit is becoming part of everyday practice for the medical profession. Most clinicians have a genuine desire to prove to themselves and to others that they provide a high quality, effective service. That sense of altruism must never be allowed to diminish.

With a few notable exceptions,[1,2] however, previous medical audit activities in many hospitals were spasmodic, ad hoc, and uncoordinated. Recent extension and formalisation of audit in most specialties is encouraging because in future medical and clinical audit will be of vital importance to the fate of provider organisations. Whether they succeed or fail will depend not only on their quality of service but also on their ability to prove their effectiveness in terms of outcomes. That is when medical audit will really start to count.

But as medical audit becomes more central to the other major changes in the way the NHS is organised and managed, it in turn will need to be organised differently. There will be an inevitable move towards clinical audit involving other professionals within the clinical team. Medical audit will be more closely linked to risk management. There will be an imperative to relate quality of care with quantity and cost. More explicit quality standards and outcome measures will be specified in contracts between health authorities and their providers. Doctors and managers will be required to share medical audit information within agreed rules of confidentiality, and, generally, managers will want to show the value of their being involved in the audit process. The box outlines the changes in the characteristics of medical audit which are likely to take place.

Up to now managers have largely watched the development of medical audit from the sidelines, partly because of clinicians' sensitivity about the issue and partly because of managers' preoccupations with a wealth of other changes occurring in the past few years. But as medical audit becomes more important to how they manage their organisation, managers will not be content to be spectators; they will want to be players in a genuine partnership with clinical colleagues. They will need to identify what they can and should do to support the audit process and what they will expect and need from audit in the future.

Past and future characteristics of medical audit

Characteristic	*Past*	*Future*
Participation of doctors	Entirely voluntary, so dominated by enthusiasts	Almost compulsory, through peer pressure, job plans, clinical directorates, and contracting process
Participation of other healthcare professionals	Limited participation, except perhaps in data collection	Widespread participation in planning systems and collecting and analysing data
Participation of managers	Little management involvement or interest	Audit central to management objectives; managers involved and interested
Planning and development of audit systems	Uncoordinated, led by individual doctors, lacking comparability	Coordinated by clinicians and managers. Integrated with general information strategies
Resources for medical audit	Little explicitly allocated—dependent on individual commitment	Resources explicitly allocated—both direct and indirect costs recognised
Relevance to organisation's objectives	Peripheral to objectives as defined by review process, authority policies, etc	Central to organisation's objectives, as defined by contracting process. Important for organisation's viability/success
Effect on organisation's performance	Little effect on performance—few changes in individual or group clinical working practices	Measurable and continuing effect on organisation's performance—clinically and managerially

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BMJ 1991;**303**:101-3