clinic, and an abnormally placed testis should be detected.¹ As some undescended testes descend spontaneously we suggest that all boys with an undescended testis at 8 months should be reviewed at 1 year and, if the testis has still not descended, referred to a surgeon so that orchidopexy can be arranged during the second year of life.

To reduce the toll of testicular cancer better health education is required as this would also benefit all potential victims, 90% of whom have normally descended testes. Self examination should be taught at an early age and may lead to earlier presentation of testicular tumours.

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Causes of lower gastrointestinal haemorrhage

EDITOR,—In the article on lower gastrointestinal haemorrhage in the ABC of colorectal diseases diverticular disease heads the list of causes of such haemorrhage in elderly people.¹ The author goes on to point out that although diverticular disease was once considered to be the most common cause of major lower gastrointestinal haemorrhage, many cases are now attributed to angiodysplasia.

Though I accept that massive bleeding may rarely occur from a colonic diverticulum, it is, I believe, a common misapprehension that diverticular disease also causes less severe intermittent blood loss from the lower bowel. In over 30 years' experience of general surgery I cannot remember a single case in which some other cause, usually a polyp or carcinoma, was not found for such bleeding. I believe that it is dangerous to attribute bleeding from the lower bowel to diverticular disease and that full investigation, usually including flexible sigmoidoscopy or colonoscopy, is mandatory.

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Pregnancy associated plasma protein A in Down's syndrome

EDITOR,—Among the maternal blood markers of fetal Down's syndrome reported so far three seem to be much more sensitive than the others. These are human chorionic gonadotrophin (both the intact molecule and its free β subunit), neutrophil alkaline phosphatase, and pregnancy associated plasma protein A (PAPP-A). Nicholas Wald and colleagues' report showing PAPP-A concentrations at 9-12 weeks' gestation to be substantially reduced in 19 pregnancies in which the fetus had Down's syndrome serves to confirm PAPP-A as a potentially important marker.¹ In the previous published series of 14 such pregnancies, however, measurements were made at 6-9 weeks' gestation,^{2,3} so that all the published data relate to a period much earlier in pregnancy than when screening for Down's syndrome is currently performed (15-20 weeks).

We therefore examined PAPP-A concentration at the later gestation in Yorkshire region's screening programme for Down's syndrome. In this, maternal blood is collected for measurement of

α fetoprotein, unconjugated oestriol, and human chorionic gonadotrophin concentration, and residual serum samples are stored at -25°C or cooler. The region is served by a single cytogenetics laboratory, whose records were used to identify 18 cases of Down's syndrome in the screened population. For each case five control pregnancies were found, matched for gestational age. All samples were retrieved from storage and assayed for PAPP-A in two analytical batches, without the person performing the assay knowing which samples were from cases. A radioimmunoassay was used at the Royal London Hospital based on a commercial antibody (Dako) and purified PAPP-A from the University of Odense. All results were expressed in multiples of the normal median (MoM) for the appropriate gestation derived from the regression of PAPP-A concentration on gestation in the 90 controls.

The distribution of concentrations in the cases was lower on average than that in the controls but not substantially so, and the difference was not significant. The 25th, 50th, and 75th centiles were 0.54, 0.87, and 1.11 MoM respectively in the cases compared with 0.69, 0.99, and 1.42 MoM respectively in the controls. The 95% confidence interval for the median in the cases (0.64 to 1.20 MoM) did not overlap with that in either the 6-9 week or the 9-12 week series (0.09 to 0.51 and 0.17 to 0.46 MoM respectively). The same reagents were used in all three series, and our results therefore suggest that PAPP-A concentration is a more sensitive marker in early pregnancy.

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- 1 Wald N, Stone R, Cuckle HS, Grudzinskas G, Barkai G, Brambati B, *et al.* First trimester concentrations of pregnancy associated plasma protein A and placental protein 14 in Down's syndrome. *BMJ* 1992;305:28. (4 July.)
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EDITOR,—Nicholas Wald and colleagues report low maternal serum concentrations of pregnancy associated plasma protein A (PAPP-A) in the first trimester in pregnancies in which the fetus had Down's syndrome.¹ They found no significant relation between the concentration and gestational age in normal women, presumably because of the limited time window (9-12 weeks), and therefore expressed their data as multiples of the median for the whole control group. Other authors have reported increasing PAPP-A concentrations over the first trimester.^{2,3} In our study (of 444 women with fetuses of normal karyotype; serum samples taken at 6-12 weeks) we used the same radioimmunoassay as that used by Wald and colleagues; we found that the PAPP-A concentration increased strikingly over this time.⁴ The relation between

the median PAPP-A concentration and gestation (expressed as days from the last menstrual period) was:

$$\log_e(\text{PAPP-A}) = 0.512 + 0.091d \quad (R^2 = 92\%, \quad p < 0.0001)$$

Should measurement of PAPP-A concentration emerge as a screening test in the first trimester accurate gestational dating will be needed to interpret the result of the test.

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AUTHOR'S REPLY,—It is recognised that pregnancy associated plasma protein A (PAPP-A) concentrations increase with gestational age during pregnancy. As M C M Macintosh and T Chard say, the relevant issue in our study is that, between nine and 12 weeks' gestation, we found no observable association between PAPP-A concentration and gestation so there was no need to generate normal median PAPP-A concentrations specific to gestation. We agree that this should not be taken to mean that gestation could be ignored if measurement of PAPP-A was to be used as a screening test.

More important is to define the gestational period over which measurement of PAPP-A concentration may be a useful screening test. Measurement of PAPP-A concentrations with an enzyme linked immunosorbent assay and using a commercial antibody to PAPP-A (DAKO) at 15-17 weeks of pregnancy in 16 pregnancies in which the fetus had Down's syndrome and 147 in which it did not (controls) indicated that the measurement is not useful at this time; the median value in the pregnancies in which the fetus had Down's syndrome was 1.02 multiples of the median (95% confidence interval 0.81 to 1.28) — that is, virtually the same as that in the control pregnancies of the same gestational age (NW, AV, unpublished data).

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Notifying contacts of people with HIV infection

EDITOR,—R A Keenlyside and colleagues report a useful survey of attitudes to tracing and notifying contacts of people with HIV infection¹; their introduction and discussion, however, show that they are unaware of the General Medical Council's clear guidelines on notification of partners introduced in 1988.²

According to the guidelines, doctors can disclose the HIV status of patients to their sexual partners without the patients' consent. Before doing so,

however, doctors must counsel the patients to disclose their HIV status to their partners themselves. Only if a patient fails to do so should the doctor disclose the HIV status to the partner. The General Medical Council emphasises that these are guidelines but not a strict code of practice. Keenlyside and colleagues' work shows, however, that 45% of consultants in genitourinary medicine providing HIV services were not aware of this.

Usually in a sexually transmitted disease clinic patients suffering from an identifiable disease are encouraged to trace contacts themselves and tell the contacts the condition they suffer from. This is done by means of contact slips issued to them by health advisers. In some cases the patients do not disclose the condition, and, to protect their confidentiality, codes instead of the names of the diseases are used on contact slips. If some patients do not disclose their conditions the doctors are bound to maintain confidentiality under the NHS (Venereal Diseases) Regulations 1974 and NHS Trusts (Venereal Diseases) Directions 1991. In the case of HIV this practice of confidentiality can be waived, according to the General Medical Council's guidelines. In fact, the duty of confidentiality is not absolute, and the law allows a doctor to breach it in the public interest.³

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Health technology assessment

EDITOR,—We agree with Bryan Jennett when he argues for more health technology assessment in Britain and, in particular, the need to disseminate this information in a form that is accessible to clinicians, managers, and the public.¹ Unfortunately, much of the evidence indicates that it is difficult to influence practitioners simply by producing and disseminating information.²

Health authorities now have a leading role in assessing the health of their populations, appraising health service options, and the prioritisation and then the placing and monitoring of contracts. This provides a potential opportunity to shape the future of health care and regulate the introduction and use of health technologies. To facilitate the purchasing process the NHS Management Executive commissioned bulletins on effectiveness.

Since January this year the School of Public Health at Leeds University, the Centre of Health Economics at York University, and the Research Unit of the Royal College of Physicians have collaborated in producing *Effective Health Care*, a bulletin for decision makers in the health service.³ These bulletins systematically and rigorously review published work on the effectiveness, cost, and acceptability of interventions.

Topics are chosen by an independent steering group of managers, directors of public health, and academics, taking into account the likely impact on the population's health, resource use, and the degree of uncertainty surrounding the intervention. The first three bulletins addressed population bone screening for osteoporosis,⁴ rehabilitation after stroke,⁵ and the management of infertility.⁶ The next two will cover surgical management of glue ear and coronary surgery and angioplasty.

Effective Health Care bulletins are designed to be short and useful and accessible to non-specialists. Altogether 30 000 are distributed free to a range of decision makers in health authorities, provider

units, and general practices in the United Kingdom, and versions appear in *GP* and *Hospital Doctor* backed up by occasional articles in the *Health Service Journal* and the media. In future dissemination will be reinforced by workshops to raise awareness of issues concerning effectiveness and to discuss how the bulletins may be used in a local setting.

This is an experiment in using purchasing power to promote change in the health service, but it must not be assumed that information, however rational and well communicated, will change behaviour. More research is needed into ways of changing the behaviour of health professionals and introducing more rationality into health care.

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Therapy for people with severe learning difficulties

EDITOR,—I am writing in response to Debabrata Chakraborti's review of the television programme "Moments of love" in the *Everyman* series as it reflects on the quality of my work.¹ The film was made to show that it was possible to work with a group of people who were failing to respond to alternative interventions. Because it was limited to a first encounter it did not, in fact, show what is unusual about this therapy, and professionals who know my work have protested about this.

What actually happens after the first exploratory meeting is that I and the students I am teaching go back to the workshop and explore how the stimuli to which they respond can be built into equipment so that they are encouraged to reach out and start exploring their environment. Equipment that I have designed is in use in most special care units in Britain. Moreover, the two training videos I have made in conjunction with colleagues in psychology, occupational therapy, and nursing departments to help carers work with people with impaired sight or challenging behaviour are used nationally and internationally.

I currently receive a grant from the Rowntree Foundation to teach carers to design and make equipment to meet people's needs; this work has been reported elsewhere.²

I agree that there is a desperate need to develop new facilities for these people and that action needs to be taken at a national level. My current work is giving me a national picture of underfunding, undertraining, and understaffing. Some levels of care are shameful.

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1 Chakraborti D. The value of human beings. *BMJ* 1992;304:1701. (27 June.)

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EC directives on medical devices

EDITOR,—An important development not mentioned in the recent series of articles on medical issues in Europe¹ is that medical devices will soon be regulated throughout the European Community. Three European Community directives regulating the safety and marketing of medical devices will come into effect from 1993 onwards. These directives are designed to protect patients and users by setting out essential requirements with which devices must conform before they can be placed on the market.

The first directive covers all powered implants, such as heart pacemakers and cochlear implants. It will come into force on 1 January next year. The second directive, known as the medical devices directive, is still in draft form and is currently the subject of negotiations among member states of the community. It will cover a wide range of products and consequently is more complex than the directive on powered implants. It is unlikely to come into force until 1995. The third directive will cover in vitro diagnostic medical devices, including diagnostic test kits and reagents, certain instruments, and products for self testing. It is likely to come into force in 1996 at the earliest.

All devices will have to satisfy the essential requirements set out in the relevant directive, and any side effects must be acceptable when weighed against the intended performance. There will be a system of classification to ensure that the level of control is proportional to the degree of risk inherent in the device. The mark "CE" on the product or its packaging will signify that the device satisfies the essential requirements and that this compliance has been appropriately validated. The marketing of devices without the CE mark will be prohibited. For the United Kingdom this will represent an important change from the present voluntary registration scheme, which is not comprehensive and is largely restricted to devices used by hospitals.

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1 Richards T, ed. *Medicine in Europe*. London: *BMJ* 1992.

Tobacco advertising

EDITOR,—In their short report Selena Gray and colleagues refer to the recent agreement to decrease the total number of signs advertising tobacco on shop fronts.¹ They conclude that the agreement is vague and therefore has little chance of being closely monitored and even less chance of being effective. As chairman of the Committee for Monitoring Agreements on Tobacco Advertising and Sponsorship, I believe that the real situation is a good deal more secure than that for three reasons.

Firstly, though the agreement does not talk in terms of the total advertising area or the proportion of shops carrying advertising, it does specify fairly precisely (clause 1.7) the types of advertising material it is intended to cover. Secondly, the decrease (by half) is required to be achieved evenly over time, by type of sign as defined in clause 1.17, and across the geographic base of retail outlets. Thirdly, immediately after the conclusion of the agreement, and as recorded in the committee's fifth report,² Coopers & Lybrand as an independent agent, was given the task of establishing both the baseline (as at July last year) against which the 50% decrease could be measured and a method of auditing the reduction process that satisfied terms of the agreement. Both these tasks have been completed. The results of the first year's audit for