established at some arbitrary level of significance we still need to decide whether the correlation reflects a causal relation. That can prove to be a somewhat more difficult task.

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¹ Doll, R, and Peto, R, *British Medical Journal*, 1977, 1, 1433.

² Tippet, L H C, *The Methods of Statistics*. London, Williams and Northgate, 1952.

³ Wulf, H R, *British Medical Journal*, 1976, 2, 878.

SIR,—Mr Richard Peto and Sir Richard Doll (23 July, p 259) reject "over-slavish adherence to rigid criteria of statistical significance" and are prepared to accept that some statistically significant associations are the artefacts of chance and that some non-significant positive associations are genuine. This is a correct and wholly justifiable use of probability statistics, as Dr G Silverman points out (23 July, p 259), but it must be recognised that it introduces a far from negligible element of subjective judgment into the interpretation of observed results.

If, as has from time to time been apparent, the same principle has been adhered to throughout the presentation of the case for an association between smoking and lung cancer, as well as other diseases, then what we are asked to accept is not the objective fact that the figures show such an association, though they certainly suggest the possibility, but that Sir Richard Doll, for example, as a result of his studies, believes that such an association exists—a subjective opinion. For myself, I find the latter assertion carries much greater conviction than the former, though it naturally falls short of certainty. I believe the conspicuous failure of the campaign against smoking is related to a consistent overstatement of the case; for a strong argument is least in need of, and is most vulnerable to harm from, tendentious fallacies that can be recognised not only by those who have studied the evidence but almost instinctively by the ill-informed. I have lost count of the number of smokers who have asked, "What do they want me to die of instead?" and the claim, for example, that each lung cancer victim will cost the country many thousand pounds is at once contrasted with the expense of long-continued geriatric care if all such hazards are avoided. People are not so easily frightened as ASH supposes, and they resent moral bullying.

It seems likely that, in time, a causative link between smoking and disease other than a statistical one will be established. Meanwhile may I quote an adaptation I made some years ago of a comment by A E Housman on another topic? Probability statistics are of use for guidance, support, and restraint. They serve as leading-strings for infants, crutches for cripples, and strait-waistcoats for maniacs.

W H ST JOHN-BROOKS

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SIR,—The interesting argument raised by Professor Hugh Dudley (2 July, p 47) and the subsequent correspondence (23 July, p 259) prompt me to raise a related point.

Five studies can each demonstrate "no statistical significance." A sixth "confirms"

them. Only on reading all does one discover that each difference veers in the same direction. Such addition of results as is possible yields a statistically significant difference.

As the really obvious problems in epidemiology and the like are being solved attention is directed increasingly to rare conditions and small differences. It is hard for any one centre to assemble enough cases to "prove" anything and co-operative studies (which the *BMJ* was publishing in the 1880s) are increasing. However, in the lack of an organised co-operative study a centre which has something to say can publish only in isolation. It is my concern that a perfectly genuine association (such as Mr Peto and Sir Richard Doll's two radiologists) so small as to need a huge series to make it "significant" may ironically be "proved" again and again not to exist.

I suggest that a report "confirming" a previous "no statistical significance" should indicate the direction, if not the quantity, of previous differences.

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Treatment of the mentally ill offender

SIR,—I wish to draw to your attention the case of a seriously maltreated mentally ill patient.

As house surgeon I admitted a young man to hospital under police custody with multiple scalp lacerations which were said to have been self-inflicted. He was semiconscious, unable to tell me what happened, and difficult to examine. I was informed he had attempted to commit suicide in a police station cell where he was detained for dangerously assaulting his mother with a knife. She had been admitted to hospital earlier with multiple injuries.

The patient's lacerations were attended to and he was admitted to the ward, guarded by two policemen, for head injury observation. He became restless and uncooperative and at times aggressive. The policemen had a job to restrain him. At one time he physically struck the ward sister and on another nearly escaped from the ward. Since we were uncertain of the nature or the extent of his head injury we were reluctant to sedate him. When he started having hallucinations we sought psychiatric advice and a consultant psychiatrist diagnosed an acute schizophrenic illness; he was given large doses of a major tranquilliser which made him a little more manageable. Both the psychiatrist and my consultant agreed that he urgently required investigation and treatment in a unit caring for mentally ill patients. It became apparent that he had a psychiatric history and there appeared to be a strong possibility that he would harm either himself or someone else unless proper medical management could be secured speedily. In addition he was physically unwell; in any case he needed care that the acute trauma ward of the hospital was unable to give. His presence was making it impossible for the staff to give adequate care to the other patients on the ward.

Arrangements were made for his transfer to the local psychiatric hospital, but this was prevented by a meeting of nursing officers of that hospital, who stated that there were inadequate night staff to look after him there. The police, who had been demanding all along to take him to court to bring charges, were unable to make arrangements for the magistrate to charge him in hospital in spite of strong medical advice that he was unfit and unsafe to travel to a court of law. The police insisted on bringing charges and we found that the only relief for the ward patients and staff was

to permit his removal into police hands. He was escorted, drugged, by five policemen into a police van and taken 20 miles to appear before the magistrate, where he was charged and then returned to be placed in the hospital wing of the local prison. His management there has been good, but facilities and staffing there are inadequate to give such a seriously ill patient.

Once in prison he became more lucid and related that he had found himself on the floor at home in a trance after a fit and thought he had been poisoned by his doctor. This was one of an increasing number of paranoid episodes he had recently suffered. On this occasion he said that he intended to go to the police for protection but he was prevented by his mother, who tried to reason with him and in the process was injured. He continued to ask after his mother's welfare and denied being suicidal. He claimed he was lonely in the police cell and wanted to explain things, and in desperation banged his head repeatedly against the bars of his cell.

Currently he remains in prison, attending court every week, on remand. Attempts have been made to transfer him to a mental hospital, but in spite of his calmer state these have been unsuccessful. In any case I am informed that he requires a further court appearance before he may go to hospital.

I suspect that this is only the tip of a very much larger problem involving the organisation, financing, and staffing of the mental health services. In spite of all the official inquiries and government papers and vast sums of money the standard of care which I was trained to give my patients is impossible to meet. Medical opinion is increasingly subordinate to administrative and legal restraints. Such priorities are signs of a sick society. It is a matter of urgency that patients, and especially the mentally ill, be permitted the care they require. I ask the support of other members of the medical profession in giving these matters publicity.

ANDREW HARRIS

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Heating human milk

SIR,—We wish to comment on your leading article on this subject (28 May, p 1372), and especially on the question whether decontamination (heating) of pooled human milk is always necessary.

At our hospital—there are about 4500 births annually—newborn infants have been given about 2400 l of human milk unheated (without pasteurisation) over the past two years. This is half of the total human milk used. The milk has been bought from the "human milk centre" attached to our hospital. During these two years about 11 000 l of human milk were donated to this centre.

Most of the milk had been brought from the homes of donors, only a small quantity being sent by them by bus, train, etc. At least once monthly a sample for bacteriological culture was taken from the milk of every donor. During bacteriological culture the milk was stored frozen. If any growth of bacteria was found more samples were taken. Samples were cultured on eosin-methylene blue and blood agar. The results are shown in the accompanying table. The most frequently found bacteria were *Staphylococcus albus* and *Bacterium anitratum*. *Escherichia coli* and *Staph aureus* were detected rarely.

The milk of those mothers whose milk samples usually had no growth of bacteria

Bacteriological cultures of human milk samples

Growth of bacteria	No of cases	Per cent
No growth	528	49
<10 000/ml	408	38
10 000-20 000/ml	88	8
>20 000/ml	51	5
Total	1075	100

was put together and used without heating. The milk with growth less than 20 000 bacteria/ml was also pooled but used only after heating. Milk with growth of more than 20 000 bacteria/ml was discarded.

We believe that the most important point in achieving "clean" milk is to give the mothers adequate instructions about how to collect and store their breast milk properly. This information can best be given at home if the milk is brought from there. The goal should be milk without bacteria. If growth of bacteria is found the reason must be discussed with the donor.

When donors are informed that "clean" milk can be given to infants without harmful heating they really try and usually succeed in keeping their milk uncontaminated. According to our experience carefully collected breast milk can be kept in a refrigerator for at least three days without any growth of bacteria. So, depending on the way milk is collected and stored, pooled human milk can also be used without heating.

The question to be answered, however, remains how much contaminated milk needs to be pasteurised and in what way.

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Yersinia enteritis and Crohn's disease

SIR,—The short report by Mr N V Doraiswamy and others (2 July, p 23) indicates that enteric infection by *Yersinia enterocolitica* is not commonly diagnosed in the UK. The report seems to imply that the diagnosis may be missed because of the superficial similarity to acute Crohn's disease and a failure to recognise, or culture, the organism. Other authors^{1,2} have also stressed the similarity of this infection to acute Crohn's disease. We have examined the incidence of serological evidence of yersinia infection in a population of patients with acute and chronic inflammatory bowel disease.

Sera were tested for agglutinins to *Y pseudotuberculosis*, types 1 to 6, and *Y enterocolitica* types 3 and 9. A screening slide agglutination test³ was performed with a 1-in-2 dilution of the sera and positive results were checked with a tube agglutination test.³ Because there is evidence of colonic involvement in this infection⁴ 72 cases of histologically proved ulcerative colitis were examined. In addition, 50 cases of Crohn's disease diagnosed by standard histological or radiological criteria were examined. The distribution of radiological Crohn's disease was as follows: affecting small bowel only, 12 cases; affecting colon only, 17; affecting both colon and small bowel, 10; definitely affecting small bowel or colon but with uncertain involvement elsewhere in the gastrointestinal tract, 11 cases. This includes patients with Crohn's

disease also suffering from ankylosing spondylitis (2), erythema nodosum (1), and iritis (1). Patients presenting acutely had repeat serological examinations 6-8 weeks subsequently.

No serological evidence of present or previous yersinia infection was found in any case studied. Our findings, which are supported by those of others,³ suggest that the incidence of yersinia infection in the UK is such that frequent misdiagnosis as Crohn's disease is improbable.

We are indebted to Dr N S Mair and Mr E Fox, Public Health Laboratory, Nottingham, for yersinia cultures and much assistance with agglutination techniques.

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¹ Weber, J, *et al*, *New England Journal of Medicine*, 1970, **283**, 172.

² Vantrappen, G, *et al*, *Gastroenterology*, 1977, **72**, 220.

³ Mair, N S, in *Recent Advances in Clinical Pathology*, series 5, ed S C Dyke, p 35. London, Churchill, 1968.

⁴ Bradford, W D, *et al*, *Archives of Pathology*, 1974, **98**, 17.

⁵ Winblad, S, *et al*, *British Medical Journal*, 1966, **2**, 1363.

Effect of calcium deposition on copper IUDs

SIR,—Dr John Newton and his colleagues (22 January, p 197) postulate that calcium deposits on copper intrauterine contraceptive devices may adversely affect their effectiveness. They say that "although the copper may not be exhausted by three years of use, it may not be available for contraceptive action." They make this suggestion on the basis of evidence of calcium deposits found on the Copper 7,¹ and on comparisons of pregnancy rates for women who replaced the Copper 7 with a new Copper 7 device after two years of use with rates for women who continued to use the initial Copper 7 into the third year. The authors found a significantly higher gross pregnancy rate in the "continuation" group than in the "replacement" group. They further noted that there was no significant difference in pregnancy rates between the "continuation" group and the original cohort of women but suggest that the "reasons for pregnancy were not the same."

The data presented, however, underscore the difficulty of reaching conclusions from studies in which the subjects are not randomly allocated to different treatments. Women who chose to replace Copper 7 devices after two years of use and women who chose to continue use of the same Copper 7 device into the third year were self-selected subjects. Not only do these two groups differ "highly significantly" with regard to the pregnancy rate in the third year of use of a Copper 7 device and show a "probably significant" difference in the expulsion rate ($t=1.65$), but they also differ significantly on three other termination factors. These are removals for "pain and bleeding" (5.3 and 1.2, with $t=2.59$), removals for "planned pregnancy" (10.0 and 0, with $t=5.88$), and removals for "other personal reasons" (5.4 and 0.6, with $t=3.35$). In all five instances the group which continued use of the same Copper 7 had higher termination rates than did the group which replaced the Copper 7 devices. Moreover, on three other removal factors, "pain"

alone, "bleeding" alone, and "other medical removals," the "continuation" group had higher estimates than did the "replacement" group. When one group has higher estimated termination rates than another on eight out of eight different factors one must conclude, even on the basis of a sign test, that the groups being compared differ importantly from each other; $P=2(1/2)^8=0.0078$.

The data presented by Dr Newton and his colleagues therefore strongly suggest that self-selection may have biased the comparison of the pregnancy rates. Because none of the women who replaced the Copper 7 device and 10% of the women who continued using the same device terminated use for "planned pregnancy" there is a strong presumption that the two groups differed in age and in parity. It is well known that pregnancy rates for inert IUDs and for copper IUDs differ by age,^{2,3} with younger women having higher pregnancy rates with the device in situ. The authors discount this factor but do not present any data on the distribution or even the mean age and parity of the groups being compared. If indeed the "continuation" group was younger then perforce the "replacement" group was older and would be expected to have a low pregnancy rate.

One must also remember that the group who continued use of the Copper 7 into the third year did not have significantly higher pregnancy rates in the third year of use than did all acceptors in the first year of use. Thus this study presents no clear evidence that the calcium deposits seriously interfered with the contraceptive action of copper in the third year.

In the United States studies of the Copper T 200 device the gross cumulative pregnancy rates for women who accepted a Copper T 200 device before 30 September 1972 were 3.4 per 100 at one year, 6.4 at 2 years, and 8.7 at 3 years.⁴ The corresponding annual gross pregnancy rates are 3.4 per 100 in the first year, 3.2 per 100 in the second year, and 2.4 per 100 for the third year of use. Moreover, the gross pregnancy rate for women under the age of 30 was also lower in the third year than in the first year. These United States data indicate that the effectiveness of the Copper T device is maintained through the end of the third year of use.

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¹ Gosden, C, Ross, A, and London, N, *British Medical Journal*, 1977, **1**, 202.

² Tietze, C, and Lewit, S, *Studies in Family Planning*, 1970, **1**, No 55, p 1.

³ Jain, A K, *Contraception*, 1975, **11**, 243.

⁴ Jain, A K, and Sivin, I, *Studies in Family Planning*, 1977, **8**, 26.

* * * We sent a copy of this letter to Dr Newton, whose reply is printed below.—ED, *BMJ*.

SIR,—In reply to Dr Sivin, there was no difference in age and parity between the "continuation" and "replacement" groups in our paper. Nevertheless, he is correct in assuming that there may be differences between these two groups. However, what we said in the paper was that the pregnancy rate could be reduced still further by exchanging the device at the end of two years while recognising that the pregnancy rate in the third year of use was identical with that in the second year of use.

Only time will tell if the calcium deposits