certification is causing our registrars great concern. The J.C.H.S.T. should announce a date when certification will be required by consultant appointment committee. If inspection takes another year it would be reasonable to expect all men to obtain a certificate from 1977. Before this date appointment committees should take no account of the scheme. Men beginning their post-Fellowship training in 1974 will then know that their training will have to satisfy the J.C.H.S.T.—We are, etc.,

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Confidentiality

SIR,—The letter of Mr. R. R. L. Pryer (14 July, p. 104) raised some extremely important issues. There are really four interrelated questions that require examination. Are the data entered into the systems indicated by Mr Pryer of value even without full identification particulars of individual patients? Does the addition of identification particulars increase the value of the data? Can the costs of such systems be justified within the overall expenditure of the health service? If the answer is yes to the first three questions, can confidentiality be safeguarded?

Information systems can be of use in patient care, in management of the health service including planning, and in research. It is difficult to see how a system without patient identification can be of any value for patient care; the addition of identification particulars can, however, assist in such procedures as scheduling patients through repeat contact (for example, using systems initiated by the input of birth notification to control immunization programmes or the follow-up of individual patients where long-term surveillance is required). Increasing use is being made of information in the general field of administration of the health services; this information is used both as part of the general management process, and also to assist with the long-term planning. A number of authors[1-3] have indicated the value of using such data where cumulative patient files are available These enable true indices of lengths of stay and readmission rate to be obtained. Only when such indices are available from cumulative files is it possible to obtain a true picture of the functioning of the health service; this is preferable to the biased view that can be obtained from event-type data, which is all that is available in the absence of identification particulars. In this situation the provision of identification particulars enables the cumulative data to be assembled on the computer file, but also provides a check on the accuracy which is greatly needed. For example, with cancer registration, where input of data may occur from a number of hospitals providing treatment for a patient, the availability of full identification particulars enables duplicate entries to be identified and adjustment of the statistics to be made. Acheson[4] has shown after a relatively few years' experience with the Oxford Record Linkage Study how the assembly of cumulative files (using the linked data) can be of considerable value for clinical, epidemiological, and genetic research. He clearly indicated that such studies could not be achieved without the provision of identification particulars sufficient to bring together on the cumulative file the repeat events occurring to an individual.

There has been a gradually increasing demand for the use of information in the fields indicated above; however, it is important to bear in mind the costs of these information systems. The conversion of the basic event-type data to cumulative files linked by identification particularly adds only a small proportion to the cost of the system, but adds greatly to the uses to which the material may be put. It is thus suggested that the cumulative data can more readily be justified than a continued collection of event-type data without identification particulars of individuals.

It appears therefore that the essential question that requires resolution concerns the ability to safeguard the confidentiality of information in such systems. One must consider the protection of these data during collection, processing, and distribution of the analyses from the system. It is relatively easy to arrange for strict security of the data on collection and processing, though there is always the need to review the arrangements made. As far as the distribution of the analyses are concerned, this can be considered in relation to the classes of information to be released, and the categories of users. A lot of the output from such systems is tabular in nature and poses no threat whatsoever to confidentiality. Some investigators will, however, request release of unit numbers in order to provide access to patient records. Each specific study must be considered by appropriate representatives of the medical profession, depending on the level at which the study is to take place. This may involve contacting consultants whose patients are involved; it may be appropriate to draw the study to the attention and obtain approval of a division of a Cogwheel system, a medical executive committee, the research subcommittee or medical advisory committee to a regional board, or at national level the Ethical Committee of the B.M.A. In addition to obtaining approval for the study in principle the individual consultants whose patient records are to be studied should each be approached. Some research workers will desire to contact individual patients, in addition to the foregoing procedure the permission of the family doctor concerned and of the individual patient should be obtained before the research worker contacts the patient. As was emphasized by the recent statement from the Medical Research Council,[5] no undue pressure should be brought to bear upon an individual patient to participate in such a study.

The questions mentioned in the beginning of this letter are easy to pose but difficult to answer, either in a short letter or a lengthy article. The above points just indicate the general approach that should be made to safeguard confidentiality on this important issue. It is essential, as Mr. Pryer suggests, that the system and the safeguards should be spelled out, and representatives of the profession should agree that these are satisfactory. Review of the precautions should be periodically undertaken, and the system and its operation should be open to inspection. It is suggested that only where an individual patient is to be contacted by a research worker should the patient's written permission for this be obtained. For a number of the systems it might even jeopardize patient wellbeing to obtain written permission for entry of these data into the information system; for instance, where information is required for entry into the national cancer registration scheme it would pose major problems if written permission for this to occur had to be obtained from the patient.—I am, etc.,

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1 Alderson, M. R., *Health and Social Service Journal*, 1973, **83**, 1524.
2 Bispham, K., Thorne, S., Holland, W. W., in *Challenges for Change*, ed. G. McLachlan, London Oxford University Press, 1971.
3 Rowe, R. G., and Brewer, W., *Hospital Activity Analysis*, London, Butterworths, 1972.
4 Acheson, E. D., *Medical Record Linkage*, London, Oxford University Press, 1967.
5 Medical Research Council, *British Medical Journal*, 1973, **1**, 213.

SIR,—Mr. R. R. L. Pryer (14 July, p. 104) is to be congratulated on his stand over confidentiality. In my experience patients are already suffering from unethical disclosure of medical information. Loss of confidentiality is an inevitable consequence of our state N.H.S., which reeks of totalitarianism.—I am, etc.,

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Prophylactic Antibiotics in Caesarean Section

SIR,—While approving of the note of caution in your leading article (23 June, p. 675) about the possibility of breeding existing organisms selectively by antibiotic prophylaxis, I wonder whether you have not been guilty of some wishful thinking. You say: "Many hospitals have introduced an antibiotic policy controlled by an infection officer. This has often been conspicuously successful in reducing the emergence of antibiotic-resistant bacteria." There are many of us who would be glad to have clear published evidence for the success of such policies, but so far as I know there is not much available.—I am, etc.,

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Bone Disease in End-stage Renal Failure

SIR,—The results reported by Dr. Joan P. Ingham and others (30 June, p. 745) concerning the incidence of osteoporosis, osteomalacia, and osteitis fibrosa in end-stage renal failure are interesting, but one wonders how meaningful they are.

The high incidence of osteoporosis (11 out of 46 patients) is surprising and is presumably partly due to the fact that osteoporosis was diagnosed when the total bone index was 21·8% or less in males and 16·7% or less in females. These figures were apparently based upon findings in a limited number of control subjects, and other workers in

this field, after studying large numbers of subjects of all ages,[1-3] would probably consider them to be unrealistically high as a guide to the lower limit of normality. It is also difficult to know what importance can be attached to the findings of a low total bone value in a narrow trephine (0·3 cm) bone biopsy sample since it is known that there may be wide variations in the individual patient depending upon the site selected.[3]

Regarding the number of patients with osteomalacia, we are told that osteomalacia was diagnosed when the osteoid index was 0·8% or more, since the index was less than 0·7% in all normal subjects. It is well recognized that it is unreliable to diagnose osteomalacia merely on the basis of an excess of osteoid. This is particularly the case in azotaemic renal osteodystrophy where excess osteoid formation may be a feature of osteitis fibrosa associated with increased osteoblastic activity even in the absence of osteomalacia. The diagnosis of osteomalacia can be difficult in these circumstances and it is necessary to take cognizance of the amount of osteoid, the width of osteoid seams, and the nature and distribution of the calcification front.[4]

Regarding osteitis fibrosa, apparently this was diagnosed and graded on the number of identifiable areas of bone "scalloping." The main difficulty here is that resorption of bone in these sick patients may not necessarily be due to osteitis fibrosa, and it is desirable to take into account the number of osteoclasts and amounts of marrow fibrosis and woven bone formation.[4]

One final point concerning the time of onset of osteomalacia in azotaemic renal osteodystrophy. Recent published work[4] based on detailed quantitative histology of bone is in keeping with the view that the first bony abnormality to arise is usually osteitis fibrosa due to secondary hyperparathyroidism, with subsequent development of a mineralization defect and osteomalacia. This concept is also consistent with the results of studies of serum parathyroid hormone levels in patients with chronic renal failure.[5]—I am, etc.,

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1 Garner, A., and Ball, J., *Journal of Pathology and Bacteriology*, 1966, **91**, 545.
2 Sissons, H. A., Holley, K. J., and Heighway, J., in *L'ostéomalacie*, ed. D. J. Hioco, p. 19. Paris, Masson, 1967.
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Q-fever Endocarditis

SIR,—In Dr. Graham W. Hayward's Croonian Lecture (23 June, p 706 and 30 June, p. 764) on infective endocarditis *Rickettsia burneti* is mentioned as a causative organism in the section on vegetations but ignored in the sections on diagnosis and treatment. Though it is not considered to be a common cause of the disease, four cases have been diagnosed in this laboratory in the past six years. It is therefore our practice to look for antibodies to *R. burneti* in a specimen of blood collected during the time blood cultures are being taken from cases of infective endocarditis. The diagnosis is made by the demonstration, not of a rising titre because this is a chronic infection, but of high titres of antibody to both phase 1 and phase 2 antigens. Dr. Hayward's recommendation that "bacteriologically negative patients should be treated as if they had a resistant organism such as the enterococcus" implies that patients suffering from Q-fever endocarditis should be treated with the ineffective combination of penicillin and streptomycin, although evidence is accumulating that other antibiotics may at least arrest the progress of the disease. Tetracycline has been used successfully either alone[1-4] or combined with lincomycin,[5] co-trimoxazole[6] or chloramphenicol.[7]

In this connexion we are able to quote the outcome of case 6 of Kristinsson and Bentall,[7] the only patient in their series who was considered unsuitable for surgery. He terminated his tetracycline treatment in December 1967, after about 10 months, and had no more antibiotic therapy. He required digoxin and diuretics to control his cardiac failure but continued working intermittently as a car park attendant. His antibody titres to *R. burneti* fell during treatment and then appeared to stabilize, the results for the last two sera being:

Date	Phase 1	Phase 2
10 December 1968	1/160	1/160
5 December 1969	1/160	1/80

He died in August 1971 after a road traffic accident. At necropsy there was mitral stenosis but the other valves were normal. The vegetations on the mitral valve were fibrosed and no rickettsiae were seen in them. Some of this tissue was inoculated into guinea-pigs; they did not develop antibodies to *R. burneti*. We suggest that this patient's Q-fever endocarditis was cured by tetracycline and chloramphenicol.

In view of the successes claimed for both medical and surgical treatment we consider that the early diagnosis of infective endocarditis due to *R. burneti* is important. The delay involved in waiting until other forms of treatment have failed may result in serious valvular damage.

We are grateful to Drs. A. J. B. Edwards, M. George, and R. B. H. Tierney for information about this patient.

—We are, etc.,

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1 Royal Postgraduate Medical School *British Medical Journal*, 1968, **4**, 40.
2 Walters J., *British Medical Journal*, 1968, **4**, 770.
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Epidemiology of Simple Hypospadias

SIR,—Professor H. Campbell and his colleagues (7 July, p. 52), using data relating to malformations notified to local health authorities in England and Wales in 1967-71, show that the incidence of hypospadias did not vary according to the month of birth. They point out that this finding differs from that reported by Dr. C. J. Roberts and Mrs. S. Lloyd (31 March, p. 768) from South Wales, where there were fewer cases than expected in pregnancies commencing in the period April-September (corresponding broadly to January-June births). Two earlier studies also gave conflicting results. One carried out by the College of General Practitioners in 1954-60[1] showed no seasonal variation, but in the United States Wehrung and Hay[2] reported an appreciable excess of cases among infants born in the first half of the year.

These inconsistencies prompted us to look at our records relating to hypospadias in Birmingham births. We examined two 10-year periods, 1950-9 and 1963-72, but since the two distributions were similar we have combined them into a single table. Like Dr. Roberts and Mrs. Lloyd we have excluded cases associated with other malformations. Expected numbers, based on the monthly distribution of all Birmingham births, represent the number of cases that would have occurred if the monthly incidence had remained constant.

Month of Birth	No. of Cases	
	Observed	Expected
January	26	26·9
February	21	24·8
March	20	28·1
April	31	26·9
May	31	27·7
June	26	26·5
July	24	27·0
August	30	25·8
September	25	25·9
October	27	25·5
November	29	23·8
December	24	25·1

The close agreement between observed and expected numbers leads us to conclude that in Birmingham, as in the country as a whole, there is no appreciable seasonal variation in the incidence of hypospadias.—We are, etc.,

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1 Slater, B.C.S., Watson, G. I., and McDonald, J. C., *British Journal of Preventive and Social Medicine*, 1964, **18**, 1.
2 Wehrung, D. A., and Hay, S., *Ibid.*, 1970, **24**, 24.

Lithium Toxicity in the Newborn

SIR,—Although reports to the Registrar of Lithium Babies (Dr. M. Schou and others, 21 April, p. 135) include two infants "floppy" at birth and one case of perinatal asphyxia out of a total of 113 liveborn infants, there have been no detailed reports published of problems encountered in the neonatal period in infants delivered to lithium-treated mothers whose serum lithium was below the toxic level of 2 mEq/l.[1] Toxic symptoms have been noted in one infant whose serum lithium level was 2·4 mEq/l. on the second day of life but whose mother's level, post-delivery, was 4·4 mEq/l.[2] Silverman *et al.*[3] noted no long-term effects in an infant whose serum lithium level was 1·1 mEq/l. at birth, but a degree of hypotonia was present for 48 hours.