Artificial Cardiac Pacemakers

SIR.—Dr. D. Vérel (4 May, p. 301) raises several interesting points concerning the choice of a system for long-term cardiac pacing, but I do not think it is correct for comparisons to be made between a nationwide survey of implanted pacemakers and the results obtained at one special centre using the induction method. It is a simple matter to select another centre using implantable pacemakers with results fully comparable to those obtained by Dr. Vérel. The paper by Mr. W. Forbes and others (6 April, p. 13) provides such an example.

The advantages in keeping the pulse generator outside the body quoted by Dr. Vérel are accompanied by disadvantages he omits to mention. Among these are the risk of displacement of the external coil and the possibility that the patient may turn off his pacemaker either deliberately or by mistake. The controls are available equally to the uninformed patients as to the informed. The prevention of competition between sinus and

paced rhythms by cessation of pacing is dangerous, since heart block frequently returns, and deaths have been reported when this policy was followed. The use of implantable demand pacemakers deals very satisfactorily with the problem of patients who return to sinus rhythm, but no demand version of the induction system is available as yet.

Dr. Vérel has misquoted my survey (6 April, p. 11) as showing that 57% of the implanted pacemakers had failed, whereas the true figure should be 41% (116 failures in 278 implanted pacemakers). Since this includes battery exhaustion it could be claimed that the Lucas pacemaker fails regularly every month, and in some cases every week.

These comments are in no way intended as a criticism of the excellent clinical results obtained with induction pacemakers, but to suggest that comparison of the survey for implantable pacemakers can only be made with a similar nation-wide survey of the induction system.—I am, etc.,

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Design for Ambulances

SIR.—Recent correspondence and articles in the *B.M.J.*¹⁻³ indicate increasing interest in ambulance design. The Ministry of Health Report⁴ on (Equipment and Vehicles) Ambulance Training and Equipment Part 2, 1967, cited the following more important design criteria for ambulances:

(1) Front wheel drive; (2) independent suspension; (3) forward control; (4) low floor level; (5) adequate interior capacity; (6) smooth ride; (7) attention to heat retention; and (8) ease of loading.

All my designs from 1959⁵⁻⁸ onwards have included these basic points and many others not yet arrived at by official reports—for example, ground loading capability and specific heat-retaining design. Ambulances should be built as simply as possible consistent with achieving prevention of death by the ambulance ride and prevention of the aggravation of the injury and illness. Ambulance

design to achieve such ends will, however, be more complex than the simplest ambulance (the horse-drawn ambulance), and certainly more complex than the relatively primitive automotive designs currently in use for ambulance work which do not achieve the required objectives. Though anticipating all major design criteria set out by the Ministry Working Party (in 1967) even in its 1959 form, no official support has ever been received for my design.

The annual home market for such a vehicle is only in hundreds as an ambulance, but since such a vehicle, particularly with low loading capability, has hosts of other uses the ambulance requirement alone is not the gauge of production requirement. The export potential of such an ambulance is very great and is never mentioned in the official reports. Surely Government committees should be cognizant with Britain's export needs.

The cost of such a vehicle would depend on the production figure. A prototype in 1963 would have cost £15,000. In 1967 the Ministry Working Party states that £60,000 is now needed to develop a vehicle. By their own criteria their projected vehicle would be practically identical with mine. In 1963 the selling price of such a vehicle would have been £3,000 to £3,500. As existing ambulance vehicles achieve practically none of the desirable requirements for an ambulance, one cannot compare the cost of a vehicle with restricted capability with one which has all the required life-saving design features. There is no existing price yardstick for an ambulance. Comparison of a real ambulance with the price of a converted commercial vehicle is not an admissible comparison.

The Ministry of Health Working Party's Report of 1967 describes my vehicle as "a vehicle capable of lowering its body to the ground," but no other descriptive data are given. The Report states that this vehicle, which has in fact front-wheel drive, independent suspension, etc., and all of the significant design features the official committee cite, is not a basis for development. They then go on to cite their own identical main design criteria but give no references or sources to the four published papers describing my designs from 1959 onwards which were available to them and which antedate their conclusions by many years.—I am, etc.,

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PETER W. BOTHWELL.

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Oral Contraceptives and Thromboembolic Disease

SIR.—I believe that in one respect Dr. M. P. Vessey and Dr. R. Doll have departed from the generally high level of objective analysis displayed in their recent article (27 April, p. 199). They note that "42% of the women who developed thromboembolic disease . . . had been using oral contraceptives for less than six months," yet in their discussion they remark that "In particular there is no suggestion . . . in this study . . . that venous thromboembolism tends to occur shortly after beginning the use of oral contraceptives." Surely anything less than six months is a fairly short time in the context of this form of drug therapy, and 42% is a not inconsiderable proportion?

I have no direct clinical concern with the prescribing of oral contraceptives, although I do have a peripheral interest in certain aspects of their pharmacology. I have been struck by the frequency with which the cases of thromboembolic disease, about which I hear (clinical impression and hearsay evidence only, I admit, and thus highly suspect), have occurred within a few months of the patients having started a course of oral contraceptives. The change in tissue properties or constitution evoked by the pill which increases the

Overall concept diagram showing trolley in position.

susceptibility to thromboembolism seems likely to be established within the first few months. Obviously it is important to know if there is a critical period of a few months (for argument's sake, between 24 and 36 weeks after commencement, corresponding to the critical period during pregnancy) after which the incidence of thromboembolism falls abruptly, or if the risk remains at the same level throughout the period of taking the pill (full allowance being made for age-dependency). In other words, if the 10 cases of thromboembolism occurring within 6 months of starting the pill are disregarded, do the remaining 16 cases constitute a significantly high incidence of the disease? Drs. Vessey and Doll's comments on this point would, I feel sure, be welcomed.—I am, etc.,

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Phenylketonuria

SIR,—Your leading article entitled "Screening Tests for Phenylketonuria" (16 March, p. 656) opens with the statement that "detection and treatment of phenylketonuria early in infancy can prevent severe and permanent intellectual impairment." This opinion, and also the underlying assumption that hyperphenylalaninaemia is incompatible with normal mental development, should be kept open, for some ambiguities must still be resolved.

As you point out, recent challenges of the efficacy of dietary treatment have been contested by E. S. Brown and H. A. Waisman¹ and by M. E. O'Flynn and D. Y. Y. Hsia.² However, Brown and Waisman do not cast doubt on the existence of phenylketonuria without mental retardation; and O'Flynn and Hsia, while recommending dietary treatment, emphasize that "the therapeutic value of the low-phenylalanine diet remains to be proved by means of a control study."

Concerning your statement that "atypical phenylketonuria," as described by L. I. Woolf *et al.*,³ requires dietetic treatment in infancy, I should like to mention that both cases described by Woolf *et al.* showed normal mental development during infancy without treatment. One continued normal into adulthood; the second had epileptic seizures, starting at the age of nine years.

In regard to legal requirements of mass screening for phenylketonuria in the United States, the Children's Bureau⁴ announced in November 1966 that 37 States had enacted legislation, with Connecticut starting its programme on 1 January 1966. Since these laws are aimed at prevention of mental retardation, they may well exert some legal pressure toward dietary treatment. Thus control studies of therapy must consider legal as well as ethical restraints. In spite of growing evidence for the need for further study of the indications and the efficacy of dietary treatment, the opportunity for evaluation may well have passed in the United States.

Recent reports underscore again the variability of biochemical and clinical manifestations in phenylketonuria, and the possible hazards of the diet.⁵⁻⁷ Reversible retardation of growth and motor and mental development, epilepsy, and hypochromic anaemia have occurred during dietary treatment, and some

fatal outcomes have been reported. In the light of these facts action should not freeze further research, and legislation should allow for evaluation and review.—I am, etc.,

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Intramuscular Injections

SIR,—The subject of the optimum site for intramuscular injections is of great importance, so it is as well that from time to time various points of view continue to be expressed. I am sure few, if any, will disagree with Mr. W. H. Beesley (13 April, p. 116) that the lateral aspect of the thighs should always be used in preference to the buttocks or the deltoid. I think, however, those who have been subjected to a prolonged period of intramuscular injections at frequent intervals will disagree that there is usually less discomfort in the thigh than in the buttock. I would say the buttock is by far the more comfortable site. It is true if the injection is given into the thigh the patient does not have to sit on the site, but on the other hand repeated injections under the tight fascia lata may lead to stiffness of the muscles and pain on flexing the knee.

The point in writing this letter is not to disagree with the optimum site of injection, as I am sure the thigh should be routinely used, but to point out that in my experience it is not correct to say the thigh is less uncomfortable than the buttock, and that there are occasions when the buttocks may have to be called into play if intramuscular injections are required for any length of time. If, then, nurses cease to be taught the correct technique of injections into the buttock and the dangers stressed, when the occasion arises when such an injection has to be made both the nurse and patient will be at a grave disadvantage.—I am, etc.,

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A. G. BUTTERS.

SIR,—In a letter to you (27 April, p. 241) Professor S. D. Rubbo and Dr. Joan F. Gardner mention the use of skin preparations such as tincture of iodine or 0.5% chlorhexidine in 70% alcohol before injections, as they "will effectively destroy vegetative contaminants and assist the removal of any spores." However, this is not so in practice, as I have shown.¹ In this paper I showed evidence that at best "virtual" sterility could be produced in 15 seconds, but that the aver-

age time between swabbing and injection was about five seconds.² According to Lowbury³ the maximum temporary reduction in the number of organisms detectable on the skin is approximately 80%, whatever method is used, although Price⁴ and Story⁵ obtained a complete kill of all skin flora after 30 seconds' swabbing. The mechanical effects of swabbing are also discussed, and no good evidence found that they are of benefit in producing sterility.

By all means avoid the buttock for intramuscular injections of adrenaline or colloidal iron, but I do not believe that swabbing of the skin as normally performed will make any injection in any way safer. I have dispensed with routine skin preparation before all injections for several years now, with no ill effects, and would commend this practice to be adopted universally.—I am, etc.,

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Birth Asphyxia

SIR,—In the article on respiratory disorders in newborn infants (27 April, p. 228) the use of intravenous sodium bicarbonate was recommended for the correction of severe metabolic acidosis. It was implied that oral administration was unsuitable because of slowness of onset of effect and the dangers of regurgitation and inhalation. While the intravenous route should be used wherever possible, circumstances may render this impracticable—for example, in domiciliary practice when the doctor is not immediately available.

We are carrying out studies to compare the efficacy of oral and intravenously administered sodium bicarbonate, and preliminary results suggest that a useful degree of correction can be obtained within one hour by the oral route. In some cases the administration of oral sodium bicarbonate has been followed by almost complete correction of severe metabolic acidosis within three hours of birth despite evidence of impaired respiratory compensation. The oral dose (approximately 1 mEq/lb. (500 g.) bodyweight of sodium bicarbonate) appears to be well tolerated and there has been no significant regurgitation. Further studies are in progress, but meanwhile we think it is perhaps too early to dismiss the use of the oral route altogether.

Incidentally, the dose of 10 ml. of 5% sodium bicarbonate recommended in the article would contain 6 mEq and not 12 mEq as stated. Our results suggest that 10 ml. of 5% sodium bicarbonate—that is, 6 mEq—gives an adequate initial correction in the full-term infant.—We are, etc.,

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** A dose of 10 ml. of 5% sodium bicarbonate would contain 6 mEq and not 12.—Ed., B.M.J.