Assisted conception on the NHS

EDITOR.—David T Baird wonders why governments have reservations about assisted conception techniques for managing infertility.¹ Surely one of the reasons is the poor quality of evidence for the effectiveness of some treatments, which we review in the most recent issue of *Effective Health Care*.²

Many subfertility treatments have not been evaluated by randomised controlled trials. For example, there is no published report of a randomised controlled trial comparing in vitro fertilisation and embryo transfer with an untreated control group (for example, subjects in whom treatment is delayed). Similarly, the view that medical treatment of amenorrhoea is highly effective is based entirely on retrospective reviews. Estimating the increase in pregnancy rate over the often appreciable spontaneous pregnancy rate that would have occurred in the absence of treatment is often difficult.³

The relative effectiveness of in vitro fertilisation and embryo transfer and other assisted conception techniques is not clear for various reasons. For severe bilateral occlusion of the fallopian tubes in vitro fertilisation and embryo transfer is the only possible treatment, but for women with at least one patent and healthy fallopian tube there is controversy over which technique is best. Well designed randomised controlled trials are needed to answer questions about the best technique for particular indications and patient characteristics.⁴

Different treatments may have different effects on the monthly fecundity and cumulative pregnancy rates. For example, prednisolone treatment of antibodies to sperm may need longer follow up before improvement in male fertility is observed. With assisted conception the effects are more rapid. Therefore, to compare treatments time must be incorporated into the analysis. Many studies, however, do not report the duration of follow up or number of cycles of treatment. Often life table analysis cannot be used appropriately because of the lack of information about non-random drop out of patients.

Small studies cannot reliably answer questions of efficacy and may result in potentially effective interventions being dismissed prematurely. To increase the size of their study some authors group together patients with various causes of infertility, but this makes interpreting the results difficult. Another approach is to use meta-analysis to pool the results of small studies. Variability in the selection of patients, treatment, and measurement of outcomes is so great among studies, however, that aggregating results can be misleading.

Lack of good quality evidence on the effectiveness of treatment for subfertility has contributed to health authorities' often sceptical stance.⁵ These treatments must be evaluated thoroughly before they become generally available on the NHS.

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Advice to authors

Priority will be given to letters that are less than 400 words long and are typed with double spacing. All authors should sign the letter. Please enclose a stamped addressed envelope for acknowledgment.

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Screening, ethics, and the law

EDITOR.—P J Edwards and D M B Hall apply sceptical and humane intelligence to the ethical problems of health screening.¹ I hope that this heralds a backlash against the uncritical zeal that has been a hallmark of the less responsible advocates of health promotion. But I offer one modification. When Edwards and Hall say that "by offering to screen . . . the doctor assumes the same duty of care as if the patient had initiated the contact" I believe that they understate the case. By offering to screen a healthy patient the doctor, I suggest, assumes not the same but a greater duty of care than if the patient had initiated the contact.

To put it crudely: when patients ask a doctor for help because they feel ill they can expect the doctor to do only his or her best. Responsibility is, in a sense, shared between the patient and the doctor so long as the doctor is acting in good faith. But the ethics that govern preventive medicine must be different.² When a doctor initiates contact with a person who is not ill then doing his or her best is not good enough, as the later part of the editorial makes clear.

Before screening the doctor ought to have objective, scientific evidence that screening will benefit the patient—good intentions are not enough. Though screening may have uncertain benefit, it results in certain harm: wasteful cost, needless anxiety, accidental complications, predictable inconvenience, and unnecessary procedures. If there is no strong evidence of benefit the doctor should leave the patient alone. To do otherwise is, it seems to me, unethical and against the patient's interest.

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EDITOR.—Specialists, general practitioners, and clinical medical officers should consider carefully the points that P J Edwards and D M B Hall make in their editorial on screening, ethics, and the law because of the implications not only for new screening procedures but also for established screening programmes.¹ It is always difficult to stop a screening programme once it has started.

Screening for congenital dislocation of the hip has been almost universal in Britain since the mid-1960s. It has depended on the reliability of subjective clinical tests—the Ortolani test and the Barlow test. Though when some people perform these tests they are reliable,² in Britain as a whole screening has not reduced the incidence of missed diagnoses.^{3,4} It is therefore essential for each area to audit its results.⁵ These results, which will vary by area, could then be included in a handout on informed consent and screening for the condition, which could be given to the parents of every newborn baby. The wording of such a leaflet must, however, be considered carefully because the vast majority of babies (99.8%) have normal hips.

This problem is further complicated medicolegally by the fact that many believe that the disease is not always detectable clinically at birth.⁶ Edwards and Hall are correct to emphasise the importance of knowing the natural course of a disease before screening is started. Also, in the case of congenital dislocation of the hip, the Barlow test might possibly be harmful,⁷ causing a further ethical dilemma.

Screening for congenital dislocation of the hip illustrates so many of the problems associated with screening. It started on a wave of enthusiasm, with no attempt being made to measure the specificity, sensitivity, or predictive value of the tests. The clinical tests used do not strictly qualify as screening tests. In West Glamorgan the division of child health has recently addressed this problem and agreed the wording of an information leaflet that will be given to parents of all newborn babies. The leaflet will reassure them but also make them aware that the babies' hips will need further screening after the neonatal stage. It will also explain which babies have an increased risk and therefore (in this area) qualify for an ultrasound scan.

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Motivating people to attend screening for osteoporosis

EDITOR.—M J Garton and colleagues obtained response rates of 54-75% for community screening for osteoporosis.¹ Repeated health screenings in Busselton, Western Australia, since 1966 have shown that response rates depend to a large extent on the potential advantages offered to those invited to attend.² The lowest rate of attendance was for Papanicolaou smear testing (57%) and the highest for general health screening (91%).

Age (years)	Observed decrease (cm)	
	Women	Men
30	0.024	0.127
40	0.410	0.596
50	1.266	1.411
60	2.592	2.572
70	4.388	4.079
80	6.654	5.932

In any future screening for osteoporosis we intend to motivate people to attend by providing data on the rate of decrease in height of people in Busselton, particularly after the age of 40. During 1966-81 serial examinations at three year intervals were conducted on nearly the entire adult population of Busselton; the heights of the 1785 women and 1544 men were measured on three to six occasions. No subject was excluded for health reasons. Random regression analysis of each person's height and age was used to estimate the expected rate of decrease in stature with age.³ Because the analysis was confined to longitudinal changes in individual people the secular trends were removed.

From the population data women's height was estimated to peak at 162.1 cm at 26.8 years; for men the average maximum height was calculated to be 174.9 cm at 21.4 years. The table shows the observed decrease in height from peak stature in women and men at ages 30-80. It was concluded that men of predominantly northern European background could expect to be about 6 cm shorter than their peak height by the age of 80, and women could expect to be 6.7 cm shorter. Such information may be a motivation to attend screenings for osteoporosis.

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Human insulin and unawareness of hypoglycaemia

EDITOR,—The three articles on loss of awareness of hypoglycaemia with human insulin in a recent issue give the general impression that there is not really a problem with human insulin.¹⁻³ Certainly all the research that has been done has not given a definitive answer, but it does suggest that there may be a problem in certain studies. Nobody, however, seems to have taken any account of what diabetic patients are saying.

I have had insulin dependent diabetes for 23 years and have taken human insulin for two periods of two and a half years each. I found human insulin awful, and my control has been much better since I resumed taking porcine insulin. I know of other diabetic patients who have felt the same, but nobody really listens or thinks that diabetic patients' opinions are of any great value. Doctors ignore this at their peril.

John E Gerich quotes the recent study by Colagiuri *et al* in Australia as being some form of benchmark in research into this problem.⁴ This study has two serious flaws in its design. Firstly, being in a study makes diabetic patients control

their disease better than they do in normal daily life. This and the fact that the patients were put on to human or porcine insulin for only one month at a time in the study, albeit under double blind conditions, mean that it is not surprising that the patients could not tell which insulin they were receiving. If they had received each type of insulin for six months or a year they might have been able to tell the difference.

This leads me to the second flaw in the study. Colagiuri *et al* say that the patients they took for the study had complained that they had lost their symptoms of hypoglycaemic awareness. If this is so it is common sense to assume that somebody else—probably a family member or close work colleague—made the patients aware of this fact; but the questionnaires were completed only by the patients themselves with no input from the family members who would have been the first to notice whether the patients had lost their awareness.

I disagree vehemently with Gerich when he says that a study should be conducted along these lines. If it is it will be worthless as well.

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Fluid replacement in diabetic ketoacidosis

EDITOR,—If, as Peter Hammond and Simon Wallis suggest, emphasis is to be given to preventing the development of cerebral oedema in diabetic ketoacidosis¹ we need a careful analysis of the optimal levels of fluid replacement. My clinical and anecdotal impression is that the pattern of presentation of ketoacidosis is changing. Either because of newer insulins or, more probably, because of the newer regimens of insulin delivery patients are presenting earlier, with severe acidosis yet not necessarily severely dehydrated. I believe that overzealous fluid replacement in these cases may be potentially, and at worst is definitely, harmful. In patients who are haemodynamically stable I adopt an initial rate of fluid replacement of 2-3 ml/kg/h, which is well below that recommended in recently published textbooks.² Problems have arisen only when doctors have not followed the local protocol.

Experimental proof of this hypothesis is difficult, but support for lower rates of fluid replacement is increasing.^{3,4} Diabetic ketoacidosis carries a significant mortality,² much greater than that from hypoglycaemia.⁵ Improvements in its management will be achieved only by careful audit of cases. In addition, I think that there is sufficient doubt about the necessity and safety of using the currently recommended initial rates of fluid replacement that a carefully controlled study needs to be performed. This will not be easy and by necessity will need to be a multicentre study, but the cardiologists have shown us the way. It is time for the diabetologists and British Diabetic Association to grasp the nettle.

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Poisoning and child resistant containers

EDITOR,—Minerva's extract from the *Journal of Epidemiology and Community Health* says that the credit for the reduction in childhood poisoning cannot go to the introduction of child resistant containers because they came into general use in 1981 and "the admission rates for poisoning with substances not in safe containers, such as berries, plants, and mushrooms, have fallen more than for poisoning with drugs."¹

This cannot be allowed to go unchallenged. In drawing a comparison between two methods of prevention it is important to limit methodological differences—in this case the use of child resistant containers. Before these containers were introduced in 1976 for aspirin and paracetamol sold over the counter for children some 7000 children were admitted to hospital with poisoning annually. These drugs sold over the counter for adults were packaged in child resistant containers the next year, and by the end of 1978 the number of children admitted with poisoning had fallen to below 2000. Admission of children from drugs not in child resistant containers had, however, remained unchanged.² So far as we are aware, the only difference between the two groups was the packaging of the drugs. If the authors of the paper can tell us of any other measures that have reduced the admissions of children to hospital by 5000 a year we would be glad to hear of it.

There is another misleading statement in the paper. Though child resistant containers "came into general use" in 1981, this was by voluntary arrangement, and they were not used anywhere near as widely as had been hoped. It is not surprising, therefore, that the rate of poisoning from drugs did not fall rapidly. The Royal Pharmaceutical Society has therefore now made it a professional requirement that child resistant containers or strip or blister packs must be used unless the recipient specifically requests otherwise.

Of course, several other factors need to be taken into account in considering the numbers of children admitted to hospital with poisoning. Poisoning from berries and so on may be less common than previously as a result of education or the criteria for admission may be stricter than formerly, or both. We remain convinced, however, that use of child resistant containers has been one of the most effective ways of preventing accidents yet introduced.

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Health service support of breast feeding

EDITOR,—Sally Beeken and Tony Waterston note the wide discrepancy between hospital policy and practice in the establishment and continuation of breast feeding in Newcastle upon Tyne.¹ Such a discrepancy was also evident in a study I carried out in Fife Health Board last year. There the