Conference Report

Randomised trials and informed consent in neonatal medicine

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Randomised trials were originally used in agriculture, and their application to man, and particularly to babies, raises practical difficulties and moral dilemmas. Recognition of these constraints but also of the need to base treatment on scientifically sound data prompted the recent discussion on randomised trials in neonatal medicine at the John Radcliffe Hospital, Oxford.

Observation versus experiment

Any new treatment should be subjected to the rigours of a proper clinical trial before it has a chance to become so entrenched that the profession is likely to judge that any such trial is unethical, said Michael Lockwood, a lecturer on medical law and ethics. But he favoured the observational approach rather than the experimental one when there is strong evidence that a new treatment is beneficial. He thus opposed the current contentious Medical Research Council trial on periconceptional folate and vitamin supplements for mothers at risk of having children with neural tube defects. The effectiveness of folate could, he believed, be established by encouraging *all* at risk women to take supplements. An unmistakable downturn in the incidence of the disease, though it might not meet the demands of the most pernickety statistician, would be good enough for him. If doctors were required to keep records of how they treat individual patients and the consequences, in a form that made proper statistical analysis possible, a vast amount would surely be learned from epidemiological studies, he claimed.

The experimental approach was stoutly defended by Dr William Silverman, former professor of paediatrics, Columbia, New York. He attacked the "myth" that randomised trials are conducted only to convince others of what the researcher already knows to be true. Every medical treatment is double edged—witness the blindness that can be the hidden cost of giving continuous oxygen to immature neonates. Paralysing confusion about the role of supplemental oxygen was only resolved by a multicentre randomised clinical trial that was completed in 1954, 15 years after the treatment was first introduced. It showed that curtailment of supplemental oxygen reduced the risk of eye damage from 23% to 7%.

It is also claimed that patients in randomised controlled trials undergo the trial for the benefit of others. Many individuals were exposed in utero to diethylstilbesterol when it was widely adopted as a promising treatment to prevent miscarriage. The offspring of controls in the formal field testing, however, were spared the agony of the risk of vaginal carcinoma. The third "myth" is that those enrolled in randomised controlled trials are obliged to take unusually high risks. But Dr Silverman asserted that about half of all new treatments tested are found to be as successful as standard treatments.

The realities of informed consent

The discussion of philosophical niceties was followed by two bracing reports from both sides of the front line. A consultant paediatrician, Dr Andrew Whitelaw from the Hammersmith Hospital, spoke of a randomised controlled trial of phenobarbitone versus placebo for periventricular haemorrhage in which parental consent was required within four hours of birth. The practical difficulties that such a requirement led to were illustrated by the case of a 17 year old mother, unsupported by a partner, who was asked to sign a consent form soon after a caesarean section.

Dr Whitelaw believes that parental consent is needed for new drugs and treatments and where diagnostic and investigative procedures cause pain or discomfort but not when two treatments already in use are being compared. He pointed out that a paediatrician can use any treatment in an individual baby, that parents often find randomisation a difficult concept to understand and accept, and that treatment decisions often have to be made at night and fast when the risks of death or handicap are high.

The other front line report came from Bel Mooney, journalist and broadcaster. She had had a son who was born small for dates in 1974, a stillbirth in 1976, and a daughter, Kitty, born in 1980 with Hirschsprung's disease. Two days after birth, when her mother was very ill after a caesarean section, Kitty required an emergency colostomy operation late at night. Bel Mooney posed the hypothetical question of what her own reaction would have been had she been asked whether her daughter could be included in a clinical trial. Despite her "catatonic trust" in the paediatrician at that time, the merest suggestion that her daughter was to be included in "an experiment" would have added to her own considerable distress. If a partner were available to decide the issue of the child's treatment, she said that there might be trouble between mother and father if things did not go well for the child. Bel Mooney had been shocked to discover that paediatricians, whom she describes as "very nice people but frequently in too much of a hurry," do not always have all the answers. But, that said, she believed that most parents could accept the operation of chance in their child's life.

Michael Lockwood agreed that in some circumstances it might be kinder not to lay the burden of consent on the parent. But he emphasised that a doctor cannot always assume passive trust—such an assumption was certainly not justified if a clinical trial was in the offing.

As William Silverman pointed out, signed informed consent was devised in the United States in the 1960s, long after clinical trials first developed. He pressed the case for the separation of two different functions—those of investigator and friend—of the physician in clinical trials. The physician "friend" should be responsible for a personal explanation to the parent. He was dubious about the motives for informed consent forms, which he described as a "CYA [cover your buttocks (sic)] device to protect the doctor rather than the patient."

Mrs Jean Robinson, lay member of the General Medical Council, suggested that issues raised by clinical trials should be discussed with parents in early pregnancy and that consent could be obtained in advance, but this was not seen as practical. The 1% of babies with

a birthweight <1500 g tend to be born to women who do not regularly attend antenatal clinics, and studies in the USA indicate that half of parents would refuse consent if it was negotiated in advance.

Ethics committees have a role in protecting infants, but to do this adequately they must have sufficient expertise to make judgements on the scientific validity of a trial—badly designed trials are ipso facto unethical. Public awareness of the controversies in randomised trials is growing. Criticism by the editor of the bulletin of Institute of Medical Ethics of the conduct of MRC trials of treatment for prostate cancer and leukaemia^{1,2} was picked up by the

Guardian.³ It can only be a matter of time before a pressure group is formed.

References

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For Debate . . .

The doctor, the patient, and their contract

II A good practice allowance: is it feasible?

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In our first paper (17 May, p 1313) we looked at the function of the existing contract in relation to the quality of care and the rewards which general practitioners receive for their work. The government's discussion document, *Primary Health Care*, proposes the introduction of a "good practice allowance" as a means of encouraging the quality of patient care by selectively rewarding those who are able to show that they achieve desired standards.¹ In this second paper we explore this proposal.

What is good practice?

The range of services offered by British general practice has been implied and described in a growing number of publications over the past 25 years.^{2,3} But the emphasis on one or other aspect of care changes in relation to rapidly changing perceptions about health care needs. For example, the increasing proportion of people aged over 75 in the population, the policy of shifting responsibility for the care of mentally ill and handicapped people from institutions to the community, the early discharge of patients from hospital, and a new emphasis on preventive medicine and anticipatory care have all had an influence on redefining priorities and creating new imperatives for standards of care. Standards themselves will rise over time. The priority given to a particular aspect of the services to patients will also change. Good practice must therefore be seen not as the achievement of fixed goals, which will be static over long periods of time, but as a dynamic movement.

Here we can only indicate a tentative framework for looking at

current standards, which might be used in allocating a good practice allowance. We suggest that standards could be created under three headings: clinical performance, anticipatory care, and the organisation of the practice.

Clinical performance

The Joint Committee for Postgraduate Training in General Practice recognises that good records are a prerequisite for good clinical standards (Letter to regional advisers, 1984). For example, training practices are expected to show that continuation sheets, hospital letters, and investigation results are attached in chronological order. Standards of care could be agreed and monitored in relation to a number of important acute and chronic conditions. Similarly, criteria for good prescribing, including monitoring long term medication, are being devised. Communication between general practice and the hospital is widely regarded as a sensitive component of the quality of care. Criteria might be agreed about the content of referral letters and the information which ought to be clearly stated. Criteria for referral might be agreed and could be audited.

Anticipatory care

For years preventive measures such as immunisation and cervical cytology have been part of public policy, and items of service payments have been made for them. It is a logical step now to make additional criteria for these same activities in terms of the proportion of the relevant population on the doctor's list for whom these services have been provided.

Anticipatory care is an integral part of clinical performance, but we believe that each activity may be differently assessed. Good anticipatory care will demand the use of a reasonably accurate age-sex register, disease or problem registers, and effective systems for call and recall. Standards could be devised for obstetric care, cervical cytology, paediatric surveillance, case finding and control of hypertension, health surveillance for people over 75, immunisation cover, and similar programmes.⁴

Organisation of the practice

Criteria for the standards of premises are already emerging: these could be extended to include equipment. The principle of information sheets for patients has already been accepted by the General Medical Services Committee and the Royal College of General Practitioners. Standards could be created in relation to accessibility: the elapse of time between the request

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