Human experimentation

Indian rules

Lucknow

To help Indian investigators plan their clinical studies the Indian Council of Medical Research (ICMR) has formulated guidelines for conducting medical research on human subjects.

The guidelines have been prepared by the ICMR Central Ethical Committee whose chairman is a legal expert and whose members include the Drugs Controller of India. Briefly, they seek to ensure that the rights and welfare of subjects participating in a trial are protected, that the benefits accruing from the research outweigh the risks to the individual, that the "informed consent" of the subject is obtained before the start of the trial, and that the investigator has the competence and experience to conduct the trial.

ICMR has forwarded the guidelines to the Indian government and hopes that they will be followed by all institutions engaged in clinical research in the country. Institutions under the aegis of ICMR have already been instructed to follow the guidelines. It is suggested that, to implement the new code, each institution conducting clinical research should form its own committee, which would consist of five to seven experienced clinicians and non-medical persons able to give advice on legal and ethical matters. These committees would then evaluate each proposal for research on human subjects by following a nine-point code. ICMR recommends that, if the ethical committees are to be effective, they should be independent bodies.

Recognizing that it may take some time for each institution to form its own committee, ICMR has offered to provide the services of an ethical committee to evaluate projects during an interim period of one year. This new role for ICMR will enable Indian institutions which do not have ethical committees to apply for funds from international agencies such as the World Health Organization, which will not consider a proposal for research support unless approved by an ethical committee.

The ICMR guidelines stress the importance of obtaining the informed consent of each subject. Although the details for obtaining consent are left to individual committees to work out, ICMR insists that the subject or his guardian should be given as much information as possible about the drug to be studied, including its side effects, and that it should be made clear to him that he is free to refuse to take part in the trial.

Indian law demands that the permission of the Drugs Controller of India is obtained before a clinical trial is performed on a new drug. ICMR proposes to hold meetings with other organizations involved in clinical research, to formulate ethical safeguards that will prove generally acceptable.

Zaka Imam

Vitamin deficiencies

Rickets at bay

Vitamin D-deficiency rickets appears to be on the decline among Britain's Asian community. The Department of Health and Social Security last week reported* a fall in the incidence of rickets among Asian children in the past ten years, but says that the disease remains a problem. Seeking to eradicate the disease, a department working party recommends vitamin D supplements for children at risk rather than the fortification of specific foods, milk or chapatti flour.

Once known as the "English disease", rickets was common in Victorian England with as many as a half of the children in poor areas in Leeds said to be suffering from it at the end of the nineteenth century. In the period 1926-42, the incidence was still high, with some 2-8 per cent of children in British cities with the condition. During the Second World War, however, rickets was almost eradicated by a programme (begun in 1943) in which all children received vitamin D in the form of cod liver oil supplements. The hope now is that the same approach could work among Asian children now at risk.

Rickets and its adult equivalent, osteomalacia, were first documented as a serious problem in the Asian community in Glasgow in the early 1960s, and since then has been observed in most of the larger Asian communities in the United Kingdom. Neither disease is notifiable, however, and data collection is not easy.

The recent decline of incidence is suggested by figures from the Hospital In-Patients Enquiry Programme and from a survey involving 130 general practitioners in areas with large immigrant populations. In 1977, in the Midlands and north of England, ten Asian children in 1,000 under the age of 16 had rickets, compared with only four per 1,000 in London. The risk factors are said to be lack of sunlight, strict vegetarian diet, poor rural background and a family history of rickets or osteomalacia. As both bone diseases are common in the Indian subcontinent, the report suggests that immigrants may bring it with them.

Thus, the department says, it should not be difficult to identify those at risk, which is why its report recommends vitamin D supplements backed up by health education. The decision against food fortification has been recommended by the department's Committee on Medical Aspects of Food Policy, which has studied the problem for four years, but will not satisfy all clinicians responsible for treating rickets in the Asian community.

The case for the more radical programme of fortifying specific target

**Rickets and osteomalacia.* Report of the Working Party on fortification of food with vitamin D, Committee on Medical Aspects of Food Policy, Department of Health and Social Security. HMSO, £3.90.

foods has fallen because legislation would be required before vitamin D could be added to specific foods such as milk or flour, and because the food policy committee has argued that there are sound medical reasons for not taking such a course. Thus there might then be excess vitamin consumption and, as a consequence, the risk of hypercalcaemia in children and possibly of cardiovascular complaints in adults.

In retrospect, the hypercalcaemia observed in young infants in Britain in the 1950s was almost certainly due to vitamin D overdosing. The department's report says that if milk were to be fortified with vitamin D, some children could well receive too much, especially if concerned parents also choose to provide vitamin supplements.

Technical problems complicate the fortification of chapatti flour — the target food best suited to the needs of the Asian community in Britain. Although vitamin D is stable in the flour, up to 50 per cent can be destroyed in cooking. Choosing the correct amount to add to flour is therefore difficult and the concentration of vitamin D needed to prevent rickets in young children might well prove a health risk to teenagers and adults.

Alastair Hay

Research development

Soliciting custom

The National Research Development Corporation (NRDC) is trying to improve its image. To that end it held a meeting in Manchester last week to spread its message among leading academics, industrialists and financiers in the north-west. The meeting was the second of its kind, the first having been held in Cambridge about a year ago, and it is unlikely to be the last.

NRDC, which exists to help exploit technological innovation in industry, clearly believes that not enough demands are being made on its funds and services and that more universities, and especially industries, should be coming to it with their ideas. It supports fewer projects in relation to the number of higher education and research establishments and industries in the north-west than in any other region — hence the choice of last week's meeting venue.

To judge from their criticisms, however, few of those involved in the business of technological innovation regard NRDC as a particularly helpful body. Many academics, who are obliged to offer NRDC first refusal of inventions resulting from publicly funded research, say that it is too bureaucratic, especially in securing legal protection for non-patentable inventions such as computer software. It is also criticized for not being sufficiently aggressive in marketing inventions, and for taking both too few and too many risks. Its high failure rate, as much as 80 per cent in some fields, can be taken either as a healthy