

cohort. In other studies of children born in 1966 to 1973, the frequency of cerebral palsy among survivors was also quite low.<sup>17-20</sup>

The eyes of all study infants were repeatedly examined in the nurseries by an ophthalmologist.<sup>5</sup> 5 of the children were blind, 3 because of cicatricial retrolental fibroplasia (RLF). The prevalence of severe bilateral visual impairment (2.1%) is calculated on the basis of the numbers seen at the age of 2 years by an ophthalmologist. However, since all but 2 of the other children were examined by a paediatrician at this age visual defect of this degree was unlikely to remain unsuspected, and the probable prevalence of blindness among survivors is 1.7%. This finding confirms that RLF remains a significant problem; these and the less serious ocular abnormalities have been reported separately.<sup>13,14</sup>

Severe sensorineural deafness requiring a hearing aid was identified in only 4 children, although many parents would not bring their children for testing. Those not formally assessed at 2 years of age had no speech or language problems and in most, free-field audiometry had been performed earlier in infancy; conductive hearing impairment, abnormal tympanograms, and abnormal tympanic membranes on clinical examination were frequent findings. A prevalence of severe sensorineural deafness of 1.5% is considered to be an accurate estimate. This rate is an improvement on the level of 3.7% reported for the 1966-70 cohort of VLBW infants from hospital A.<sup>16</sup>

18.0% of the entire cohort were classified as having one or more major handicap; all children with cerebral palsy were included in this category so that our data would be comparable to those in other reports. Unfortunately, there is no uniform definition of major handicap: a more realistic appraisal of our cohort would be achieved by excluding the 12 children with mild cerebral palsy and an MDI or Stanford-Binet score above 78, but including in the severely handicapped category 1 girl with arthrogyriosis. With these adjustments, 43 (14.4%) children have a moderate or severe functional handicap. Some children were classified as handicapped solely because of a low MDI, but in each of these children, the independent paediatric assessment also indicated severe developmental delay.

In children aged 2 years handicaps likely to result in permanent disability can be identified with reasonable accuracy. It is too early to assess the prevalence of mild handicap in the remainder of the children; assessment at primary school age will be necessary to obtain this information.

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References continued at foot of next column

## Round the World

From our Correspondents

### West Germany

#### ATTITUDES TO CONTROLLED CLINICAL TRIALS

ASK a German doctor whether the controlled trial is an essential aid to clinical work and the answer is unlikely to be a firm Yes. Most have had no undergraduate or postgraduate training in the subject—or even experience in the ethically much less problematical matter of designing work in animals for the M.D. thesis. Now, in professional life, the doctor is a prey, week by week, to sharply conflicting news and views.

On the one hand, controlled trials are seen as praiseworthy in being "scientific"; they are mustered in support of some 400 drugs registered every year by the German drug regulatory authority;<sup>1</sup> they are recommended by the main scientific societies;<sup>2,3</sup> they are invoked by drug companies ("a controlled trial has shown . . ."); and they are at least not excluded by German law (*Arzneimittelgesetz*, 1978).

On the other hand, at least six reasons are advanced for rejection of controlled trials. They have come under fire from some American workers (again, the voice of science).<sup>4</sup> The activities of participating doctors have been compared by the Press<sup>5</sup> with those of concentration-camp criminals ("human sacrifice, medical technocrats"), and such taunts are not easily countered by lone research-workers. More seriously, a single instance of death in the control group of a trial has been categorised by a professor of criminal law as assassination,<sup>6</sup> and ten court cases are under way against the conductors of trials.<sup>7</sup> The sheer number of trials (3-5 per substance) is said to contribute to an anonymous, mass produced, and heartless medical system; and for this and other reasons they have been assailed by critics within

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the profession,<sup>8,9</sup> whose impact derives partly from the public distaste for "authority". Last but not least, controlled clinical trials are rejected by the manufacturers of products which lack activity ("We help the individual subject, not the masses").

There is no simple answer to these philosophical and practical dilemmas, but some guidance is on offer.<sup>2,10,11</sup> Firstly, more intellectual power should be devoted to the clinical aspects of a trial. Whereas statistical, legal, and ethical aspects now receive ample, if not undue, attention, clinical trials often fail because relevant existing information has been neglected, because clinically unimportant end-points have been selected and known prognostic factors omitted, because clinical pharmacology has been ignored, because the methods of assessment are imprecise, because follow-up is incomplete, and because quality control is lacking. Not every clinical question has to be answered by a placebo-controlled trial. Clinical trials fall into different categories, and the distinction is relevant to the question of informed consent. Placebo controls apart, there is the comparison of two standard treatments, the comparison of an advanced new therapeutic or diagnostic regimen with routine management, and the trial involving human experimentation (such as heart transplantation). For trials of standard treatments administered routinely, informed consent about randomisation is *not* considered absolutely necessary.<sup>11</sup>

Remarkably, the first West German workshop on clinical trials was established by the Surgical Society; and this trend is reflected in the establishment of a chair of theoretical surgery at Marburg.

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## United States

### SENATOR KENNEDY AND A NUCLEAR FREEZE

THE latest Gallup opinion poll shows Democrats across the nation strongly favour Senator Edward Kennedy as their party's Presidential nominee in 1984. In accordance with custom, Mr Kennedy won't say this early whether he will run for it again. There is more pressing business at hand, anyway. His 1982 re-election campaign in Massachusetts for another six-year term in the U.S. Senate begins in July. This promises to be a rigorous effort, even though the Senator's likely Republican opponent, Mr Raymond Shamie, is a political unknown. A wealthy businessman, Mr Shamie is said to have collected \$4 million to help correct his problem of name recognition. Furthermore, Mr Shamie's polls say Mr Kennedy's popularity is in decline (another poll disputes this).

Whatever Mr Kennedy's Presidential ambitions, politicians will be watching this contest as a preview of his performance potential for 1984. Of special relevance will be one of Mr Kennedy's favourite political issues: his proposal, along with a Republican co-sponsor, Senator Mark O. Hatfield of Oregon, for the United States to enter an agreement with the Soviet Union to freeze the testing, production, and development of nuclear weapons and new aircraft designed to deliver nuclear weapons. This proposal lacks the necessary White House and Congressional support to achieve reality, but there are indications of widespread popular support. Town meetings and city councils around the country have approved their local version of a freeze proposal. A freeze will be on the November ballot in California and other states. Surveys indicate that 60–70% of the population favour a freeze.

Mr Reagan and leaders in Congress say a freeze now is out of the question. They say it would freeze the arms buildup at a point favourable to the Soviet Union; they appear to suggest the idea is simplistic. They are, however, handling the matter with extreme

caution. Voters do not like to be told it is all too complicated for them to understand. So Mr Reagan and his supporters get around it by saying they, too, are for a freeze—after the current \$1.5 trillion arms buildup is completed. Senator Kennedy has this comment: "The President says, in effect, that we have to build more nuclear bombs today in order to reduce the number of bombs tomorrow. That is voodoo arms control."

What is remarkable about all this is that Mr Kennedy, less than two years after his party decisively rejected his bid for the Presidential nomination, is again on the offensive. Actually, Mr Kennedy's ideas have not changed. The times have changed. Many people are more worried about nuclear war than they were two years ago. The President, along with Secretary of Defense Caspar W. Weinberger and Secretary of State Alexander M. Haig Jr, have inferentially acknowledged these fears in the public by toning down or foregoing altogether previously bellicose, threatening language. Even more directly, people are dismayed over the depressed economy with its record high unemployment levels, business failures, farm discontent, and high interest rates. Republican Wall Street seems uneasy.

The conservative nature of the U.S. electorate should never be discounted. Americans tend to vote heavily against candidates on the left, such as George McGovern, or on the right, such as Barry Goldwater, when they suspect that any strong deviation from the status quo is contemplated. A candidate with the name and Irish charm of Edward Kennedy, however, is something else again, even if he does sound like George McGovern. If the current political mood persists or intensifies, Senator Kennedy might be a strong contender for the Presidency in 1984.

### QUESTIONS ABOUT THE DEPARTMENT OF AGRICULTURE

THERE are some disturbing events in the Department of Agriculture under the present Administration. A report from the Department has recommended that, in the appointment of advisers to examine scientific research applications, it was advisable to consider their political views and affiliations and to suggest only individuals whose views correspond with those of the present administration. This was an astonishing suggestion in a democratic country, in which scorn has often been expressed for the pretensions of Soviet "science" in the days of Stalin. Immediate criticism was forthcoming from scientists of all shades of opinion and the report was promptly recalled and disavowed by the Secretary for Agriculture.

But suspicions that there are strange influences in the Department have been increased by the controversy in the American Dietetic Association over its relationship to the Department. The Association had been protesting against the Administration's proposals over the deregulation of nursing homes. The Association's leaders supported President Reagan's cuts in food stamps and school meals, to the fury of many members, and this disquiet has been rekindled by the proposal that the Association should take over the publication of the Department of Agriculture's new book on food. One might have thought this a sound move, did one not know of the controversy over this publication. One chapter deals with weight reduction and others on how this might be achieved by a reduction in the consumption of fat, fatty products, eggs, and milk, with suitable menus to accomplish these ends. The Department intended to publish the book, but there was internal opposition, as well as intensive lobbying by the meat, egg, and dairy producers. Indeed the Under-Secretary, a past president of the American Meat Institute, said it would be published only "over my dead body". Whether to prevent his demise or not, the Department found that it had not the funds to publish the book. Perhaps the reaction of the public was anticipated, for, since the reduction in deaths from heart disease and strokes is widely attributed to just those measures that it was decided to cut out of the book, severe criticisms might be expected. The Association now wants to publish the book but without the information on fat and cholesterol, so that the public will be advised to eat meat for breakfast, perhaps with eggs. These events are aggravating some members of the Association and raising some questions about the advice given to the Administration and the influences brought to bear on the Department's decisions.

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