hope that enlightened editors will take up the challenge; the lead must come from an established, prestigious journal that can afford to be choosy.

Conclusion

Publication bias is endemic and will remain so as long as the sample sizes commonly used in research are too small and the methods used to assess adequacy of sample size are deficient. Assessment by a priori criteria—in particular, systematic peer review at the planning stage—would result in a much tighter measure of control over the quality of published work, with the prospect of improvement in study design in general and statistical power in particular.

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Medicine and the Media

AT THE ANNUAL scientific meeting of the British Paediatric Association last year the prize for the best paper presented by a young paediatrician went to a member of a research group from Oxford. Papers offered for the annual meeting are examined by the association's academic board not only for their scientific worth but also for adherence to ethical standards. This paper, later published in the *Lancet*,[1] has now been condemned by certain sections of the press and by a group of members of parliament. What was the work so condemned?

Preterm infants of low birth weight live at considerable risk, particularly of cardiorespiratory failure, and the risk is increased if they have to undergo an operation. Clinical experience suggested that deep anaesthesia and narcotic analgesics would increase the risk. That and the belief that such infants have a poor perception of pain because of lack of myelinisation in the central nervous system led to the conventional practice of anaesthesia with nitrous oxide and muscle relaxants combined with artificial ventilation. In a study of 40 published reports the Oxford team found that three quarters of newborn babies undergoing surgical ligation of patent ductus arteriosus had received muscle relaxants alone or with nitrous oxide.

In the preterm infant with a poor or absent ability to cry it is difficult to tell clinically whether pain and stress are being experienced, but newer biochemical methods that detect hormones and intermediary metabolites associated with stress now make the assessment of stress more possible and prompted a re-examination of the problem by the Oxford team. The team wanted to find out whether adding a little narcotic analgesic to the accepted anaesthetic regimen might prove beneficial rather than harmful. Using these metabolic methods, they therefore compared the response to surgical ligation of patent ductus arteriosus carried out under the conventional regimen with and without the narcotic analgesic fentanyl. The possibility that fentanyl might adversely affect respiration and circulation postoperatively was also studied.

A randomised trial was designed with help from the National Perinatal Epidemiology Unit in Oxford to ensure that the results were statistically valid and that a meaningful result would be recognised as soon as possible. After only eight babies in each group had been operated on the results showed that the new regimen was significantly superior to the old not only in reducing the stress response estimated biochemically but also in improving the postoperative state. Thus for the first time good scientific evidence was produced of the need to provide deeper anaesthesia during operations on these tiny infants.

This research was commended by the distinguished American paediatrician Dr William Silverman, author of the widely acclaimed book *Human Experimentation: A Guided Step Into the Unknown*.[2] He wrote that the Oxford workers "deserve a loud vote of thanks for the ethically sound effort to subject to a rigorous test opinion based on long standing practice. And their call for further study should not fall on deaf ears. It is indeed urgent to determine the pathophysiological consequences of unrelieved pain and suffering inflicted during everyday care of newborn babies."

Members of the British Paediatric Association were thus amazed and the doctors who had done the work bewildered and distressed when after a distorted report in the *Daily Mail* entitled, "Pain-killer shock in babies' operations" (8 July) this work became the subject of a condemnatory "press release: for immediate publication" issued by some members of parliament forming the All Party Parliamentary Pro-Life Group. The *Lancet* article appeared in January, the story in the *Daily Mail* in July, and the press release from the members of parliament in August. The press release was entitled "Inhumane baby operations slammed" and the first paragraph stated:

"Fourteen members of parliament have demanded an inquiry into trials in which sixteen premature babies were given open heart surgery, eight of them without the use of pain killers to test whether or not the babies could experience pain."

The press release then said that the General Medical Council was being asked to investigate these trials with a view to bringing those responsible before its disciplinary committee. It continued:

"In a statement Sir Bernard Braine said:

'The trials seemed to us to be even more barbarous when one considers that the babies being tested for pain were given curare, a paralysing drug, so that they would have been unable to kick or struggle even if they were in agony, the obvious intention being to keep them immobile at all costs throughout the operation. Apart from this they were given only nitrous oxide (laughing gas).'"

Implying misleadingly that wisdom acquired from the research existed before it was carried out the statement went on:

"Not surprisingly post-operatively they fared far worse than the eight babies who were given pain killers. Two of the disadvantaged babies suffered from hypotension, two showed poor peripheral circulation—both of which can be indications of shock which most

certainly could have resulted from extreme pain; two others suffered from brain haemorrhage—whereas none of those babies given pain killing drugs experienced any such ill effects."

Taken up by the national press this press release resulted in headings such as: "Barbaric! MPs' anger over baby operations. No painkiller drugs for tiny heart patients used in research trial" (*Daily Express*, 5 August); "Babies in 'barbaric' pain trials" (*Universe*, 7 August); "MPs attack 'paralysing' pain tests on babies" (*Today*, 5 August); "MPs concerned by surgery on babies" (*The Times*, 5 August); and "Baby 'pain trials' row (*Northern Echo*, 5 August).

Death or lifelong disability are unfortunately the common fate of preterm infants of low birthweight, particularly those further compromised by additional congenital abnormalities as with the babies studied in this research. Every day paediatricians are having to take difficult decisions on whether, with a view to improving the chances of preterm infants, uncomfortable or distressing procedures have to be imposed on them. Only from research can improved practice emerge, and the fortunate outcome of this Oxford research was that it showed that not only did a narcotic analgesic relieve short term stress but also—contrary to so much contemporary belief—it improved rather than compromised the postoperative state.

Research on preterm newborn infants raises difficult ethical issues. The ethical debate legitimately extends beyond paediatricians and doctors, but it is irresponsible for laymen to presume to interpret medical information when they are not competent to do this. The press release of the members of parliament used intemporate language and made many mistakes: the Oxford trial was described as one in which premature babies were "given open heart surgery" when open heart surgery was not performed; the surgery was said to be performed "without the use of pain killers" when all the babies were anaesthetised with nitrous oxide; the trial was said to "test whether or not the babies could experience pain" when the object was to ascertain whether accepted procedures were causing previously undetected stress; the research was called "barbarous" when it was caring; and the press release said that curare was given so that the babies "would have been unable to kick or struggle even if they were in agony, the obvious intention being to keep them immobile at all costs throughout the operation" when the function of the curare was to enable artificial respiration to be carried out during the operation.

These doctors' research deserved the highest commendation. It was done with the written informed consent of the parents, was designed to reduce suffering in newborn infants, was of high scientific standard, was completely ethical, meant that eight out of the 16 babies in the trial received an improved treatment, and will confer benefit on many babies yet unborn. We are disturbed that members of parliament should use their position to stigmatise valuable medical research and the doctors who carried it out by issuing an inaccurate and defamatory press statement and that the press should so misrepresent and sensationalise what was done. Public retraction of these statements and public apologies to the doctors concerned seem the least that should be done to correct these misleading pronouncements. Perhaps, too, the All Party Parliamentary Pro-Life Group will acknowledge the essential part that such research has played in improving the prospects of life of preterm babies.—J O FORFAR, president, British Paediatric Association, and A G M CAMPBELL, chairman, British Paediatric Association Ethics Advisory Committee, London.

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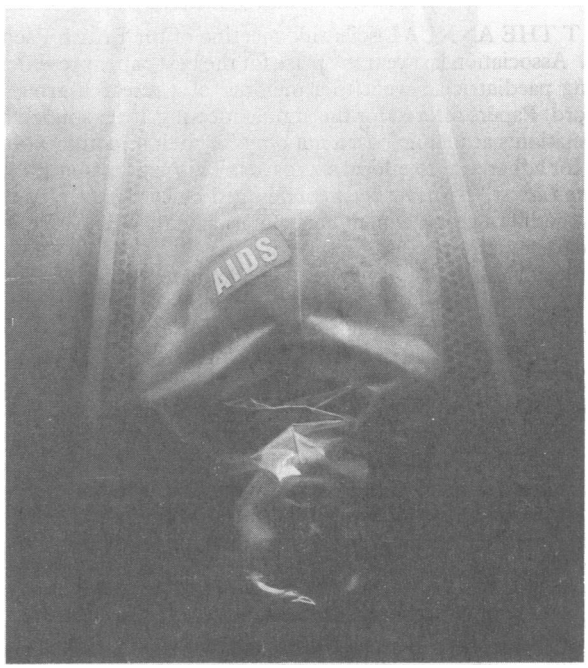
THE GOVERNMENT'S initial campaign in the mass media on the acquired immune deficiency syndrome (AIDS) featured tombstones and sombre imagery. The latest phase, launched on 2 September, consists of a £5m initiative that focuses on the dangers of drug users who share infected injecting equipment spreading the human immunodeficiency virus (HIV). The new campaign is deliberately designed to shock. One warning depicts a body in a plastic bag. A poster shows a bloodstained syringe.

As one would expect with any campaign related to such sensitive topics as intravenous drug use and AIDS it has received a mixed response. The press has been generally mildly favourable, though some people have criticised the style as "over the top" or even offensive. Some were upset by one of the campaign's more memorable slogans: "It only takes one prick to give you AIDS."

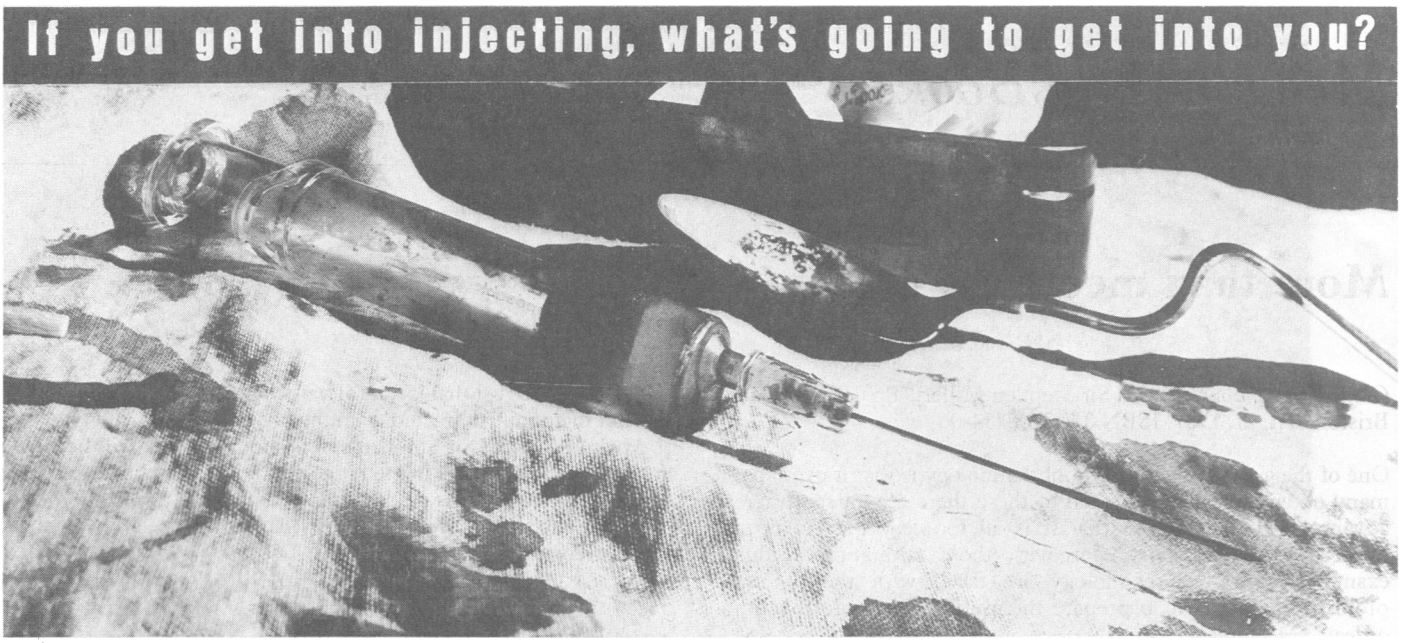
The potential seriousness of the rising AIDS epidemic cannot be exaggerated, and the government is to be congratulated for responding to this phenomenon with commitment and vigour. AIDS is so new that it is uncertain which are the most fruitful forms of preventive action. There are, however, some grounds for urging a degree, not of inaction, but of caution.

Health education is fraught with problems. People are often chronically irrational, even perverse, and indulge in risky or unhealthy pursuits for a confusing and conflicting variety of reasons. Past health promotion exercises that have attempted to deter illegal drug use or problematic drinking have produced disappointing results—often they have been ineffective or even counterproductive.[1-7] Even in relation to cigarette smoking (which has declined) the effect of health education is unclear.[8] Available evidence has led many authorities to regard expensive mass media campaigns as fruitless. The Advisory Council on the Misuse of Drugs emphasised this view in its report on *Prevention*.[9]



Notwithstanding such objections a national antidrug campaign was launched in 1985 that in effect adopted precisely the type of strategy which the advisory council had warned against. The Health Education Council (for England and Wales) declined to participate in such a venture, and its subsequent replacement by the Health Education Authority was regarded by some observers as, in part at least, the penalty for displaying such independence. It is difficult to find anyone—clinicians, counsellors, educationalists, or researchers—who has a positive attitude to that "Heroin screws you up" campaign. This exercise was evaluated in such an inadequate way that its effects, if any, remain a mystery.[10]

There are powerful justifications for any government to be worried about illegal drug use and even more worried about AIDS. Few people would maintain that the best policy is one of inaction. Attempts must be made to devise effective education or other types



of preventive strategy. Even so, a word of warning is needed. Drug education and health promotion are imperfect technologies that should be used with care and if possible should also be assessed. High profile mass media campaigns are politically attractive because they are conspicuous tokens of concern and commitment. The question is "do they work?" During the past 20 years few costly health promotion campaigns in Britain have been properly evaluated. This is unacceptable.

Moreover, attempts to question the effectiveness of such exercises have invariably provoked not a determination to evaluate future ventures but genuine surprise and annoyance. Health education is widely perceived (rightly) as worthy and (wrongly) as totally effective. Experience suggests that individual campaigns are unlikely to deter young people from using illegal drugs and that shock tactics have been unproductive. We are surprised that this new campaign adopts such shock tactics. In addition, while the message on AIDS is clear there is an implied "heroin screws you up" theme that may alienate rather than persuade young heroin users.

We hope that this campaign and its successors are effective. We hope, too, that this and subsequent ventures will be objectively and competently evaluated. The results should also be made freely available and used to guide future policy. The full proposed AIDS campaign when completed will have cost £20m. It would be a tragedy if the only beneficiaries are advertising executives.—GELLISE BAGNALL, MARTIN A PLANT, MOIRA A PLANT, research fellows, Edinburgh.

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CLIVE JERMAINE IS 21, intelligent, mature, self assured, quick thinking, verbally fluent, and down to earth. When he was 15 he developed a spinal tumour and had an operation that rendered him paraplegic. He was told that he had months or a few years to live, and the consequence was that he wrote a play for television, *The Best Years of Your Life*, which was first shown in May 1986 and repeated on 2 September (BBC2). The next evening there was a documentary about Clive, his play, his thoughts and experiences, and the media and public reaction to the play.

The play was about a young footballer who suffered from the same illness and who died. He lived with his father and slightly older brother, their mother having been killed when the brothers were young. The brother tried to help him, but the father took refuge in drink. In real life Clive's own father had opted out after two years, and he was closest to his grandmother. She had given him courage and strength and had encouraged him while he was writing the play, but she had then died of laryngeal cancer.

The play was a well written and moving story. It showed the emotional difficulties of the family and emphasised the need of the patient with cancer for support and understanding. It received critical acclaim, and over 300 people wrote to Clive to express their appreciation. The story of the play and of Clive's own disease was featured on television news, and he was interviewed on Breakfast Television by Selina Scott: "So you're faced with the prospect of dying very soon. How do you stop yourself sinking down into depression?" Interviewed for the documentary, Clive admitted that he and his family had on occasions found the media questions and voyeurism harrowing, though on television he never lost his composure. One episode that had a deep effect on him was his grandmother's death and the fact that the next day, in the middle of his grief, people in the street were singing and the world had not noticed—"Once you die you're nothing. The world goes on regardless."

When he was asked why he wrote the play and agreed to appear in the documentary he had two answers. Firstly, he wished to educate people about cancer and the needs of people who suffer from it and to help do away with "the taboo." Secondly, he felt a need to achieve in the life remaining to him—to do something to be remembered by. He has had much success with both objectives.—DOUG ADDY, consultant paediatrician, Birmingham.