Archives of Disease in Childhood, 1986, **61,** 317

Editorial policy

The numbers game

Editors are distressed when they have to reject a careful piece of work because the number of subjects studied has been too small to draw any conclusion. There are some unpredictable reasons for a short fall in numbers. An epidemic when the research was conceived may disappear suddenly when the research fellow arrives, and it may be impossible to recoup those wasted early months, especially if there is a fixed grant. The research fellow may become pregnant or ill or be enticed to a post essential for his or her future career when the project has not been completed. The study may be more complicated or costly than was anticipated, and these factors may reduce the number of children that can be studied.

In most papers that we receive and have to reject none of these factors are present. If a statistician had been given a minimum amount of information before each project began he could have predicted that an adequate number of subjects could not have been recruited because insufficient numbers of patients with that problem were seen in the unit.[1] A statistician may show that the numbers are too small to show a statistical difference between groups. He will warn the unwary about the risk of missing a large therapeutic difference between groups, despite no statistical difference, where numbers are small (type 2 error). It is clearly unethical to begin a project without the assurance of a statistician that it will be scientifically sound, and, in these days of shortage of research funds, it is incredible that grant giving bodies do not insist on this assurance before acceptance. We consider it unfair to publish these preliminary communications from which no definite conclusion can be drawn, although we know that a considerable amount of meticulous work has been performed. Some authors admit candidly that the number of subjects studied has been too small. This saves the editor and referee from having to ferret out this fact, but this admission does not eliminate the defect.

Single case reports, particularly when they are describing side effects of drugs, are difficult to evaluate. Two cases make a series, and it is possible to join with other authors to make a larger series by contacting the Committee on Safety of Medicines. We recommend that the maximum number of relevant facts should be recorded when a paper describing new side effects of a drug is being written.[2] If the side effect is due to coincidence rather than the drug a potentially helpful agent can be given a bad name without good reason and be withdrawn by the manufacturer for fear of litigation. This danger has to be balanced by rare side effects that may only occur after a drug has been used extensively and may only be found in a small number of patients in the early stages of the use of the drug.

Editors bask in a special glow when they publish a new discovery, even if it is only the sound of the first cuckoo. They are constantly worried that in their enthusiasm for the novel they will justifiably earn that avian epithet.

References

[1] Altman DG. Size of clinical trials. *Br Med J* 1983;**286:**1842–3.
[2] Venulet J. Improving reports of adverse drug reactions. *Br Med J* 1984;**289:**898.