

The scandal of poor medical research

We need less research, better research, and research done for the right reasons

What should we think about a doctor who uses the wrong treatment, either wilfully or through ignorance, or who uses the right treatment wrongly (such as by giving the wrong dose of a drug)? Most people would agree that such behaviour was unprofessional, arguably unethical, and certainly unacceptable.

What, then, should we think about researchers who use the wrong techniques (either wilfully or in ignorance), use the right techniques wrongly, misinterpret their results, report their results selectively, cite the literature selectively, and draw unjustified conclusions? We should be appalled. Yet numerous studies of the medical literature, in both general and specialist journals, have shown that all of the above phenomena are common.¹⁻⁷ This is surely a scandal.

When I tell friends outside medicine that many papers published in medical journals are misleading because of methodological weaknesses they are rightly shocked. Huge sums of money are spent annually on research that is seriously flawed through the use of inappropriate designs, unrepresentative samples, small samples, incorrect methods of analysis, and faulty interpretation. Errors are so varied that a whole book on the topic,⁷ valuable as it is, is not comprehensive; in any case, many of those who make the errors are unlikely to read it.

Why are errors so common? Put simply, much poor research arises because researchers feel compelled for career reasons to carry out research that they are ill equipped to perform, and nobody stops them. Regardless of whether a doctor intends to pursue a career in research, he or she is usually expected to carry out some research with the aim of publishing several papers. The length of a list of publications is a dubious indicator of ability to do good research; its relevance to the ability to be a good doctor is even more obscure. A common argument in favour of every doctor doing some research is that it provides useful experience and may help doctors to interpret the published research of others. Carrying out a sensible study, even on a small scale, is indeed useful, but carrying out an ill designed study in ignorance of scientific principles and getting it published surely teaches several undesirable lessons.

In many countries a research ethics committee has to approve all research involving patients. Although the Royal College of Physicians has recommended that scientific criteria are an important part of the evaluation of research proposals,⁸ few ethics committees in Britain include a statistician. Indeed, many ethics committees explicitly take a view of

ethics that excludes scientific issues. Consequently, poor or useless studies pass such review even though they can reasonably be considered to be unethical.⁹

The effects of the pressure to publish may be seen most clearly in the increase in scientific fraud,¹⁰ much of which is relatively minor and is likely to escape detection. There is nothing new about the "massage" of data or of "data torture," as it has recently been called¹¹—Charles Babbage described its different forms as long ago as 1830.¹² The temptation to behave dishonestly is surely far greater now, when all too often the main reason for a piece of research seems to be to lengthen a researcher's curriculum vitae. Bailar suggested that "there may be greater danger to the public welfare from statistical dishonesty than from almost any other form of dishonesty."¹³

Evaluation of the scientific quality of research papers often falls to statisticians. Responsible medical journals invest considerable effort in getting papers refereed by statisticians; however, few papers are rejected solely on statistical grounds.¹⁴ Unfortunately, many journals use little or no statistical refereeing—bad papers are easy to publish.

Statistical refereeing is a form of fire fighting. The time spent refereeing medical papers (often for little or no reward) would be much better spent in education and in direct participation in research as a member of the research team. There is, though, a serious shortage of statisticians to teach and, especially, to participate in research.¹⁵ Many people think that all you need to "do" statistics is a computer and appropriate software. This view is wrong even for analysis, but it certainly ignores the essential consideration of study design, the foundations on which research is built. Doctors need not be experts in statistics, but they should understand the principles of sound methods of research. If they can also analyse their own data, so much the better. Amazingly, it is widely considered acceptable for medical researchers to be ignorant of statistics. Many are not ashamed (and some seem proud) to admit that they "don't know anything about statistics."

The poor quality of much medical research is widely acknowledged, yet disturbingly the leaders of the medical profession seem only minimally concerned about the problem and make no apparent efforts to find a solution. Manufacturing industry has come to recognise, albeit gradually, that quality control needs to be built in from the start rather than the failures being discarded, and the same principles should inform medical research. The issue here is not one of statistics

as such. Rather it is a more general failure to appreciate the basic principles underlying scientific research, coupled with the "publish or perish" climate.

As the system encourages poor research it is the system that should be changed. We need less research, better research, and research done for the right reasons. Abandoning using the number of publications as a measure of ability would be a start.

DOUGLAS G ALTMAN
Head

Medical Statistics Laboratory,
Imperial Cancer Research Fund,
London WC2A 3PX

1 Altman DG. Statistics in medical journals. *Stat Med* 1983;1:59-71.

2 Pocock SJ, Hughes MD, Lee RJ. Statistical problems in the reporting of clinical trials. A survey of three medical journals. *N Engl J Med* 1987;317:426-32.

3 Smith DG, Clemens J, Crede W, Harvey M, Gracely EJ. Impact of multiple comparisons in randomised clinical trials. *Am J Med* 1987;83:545-50.
4 Murray GD. The task of a statistical referee. *Br J Surg* 1988;75:664-7.
5 Gotzsche PC. Methodology and overt and hidden bias in reports of 196 double-blind trials of non-steroidal antiinflammatory drugs in rheumatoid arthritis. *Controlled Clin Trials* 1989;10:31-59.
6 Williams HC, Seed P. Inadequate size of "negative" clinical trials in dermatology. *Br J Dermatol* 1993;128:317-26.
7 Andersen B. Methodological errors in medical research. An incomplete catalogue. Oxford: Blackwell, 1990.
8 Royal College of Physicians. *Guidelines on the practice of ethics committees in medical research*. London: RCP, 1984.
9 Altman DG. Statistics and ethics in medical research. Misuse of statistics is unethical. *BMJ* 1980;281:1182-4.
10 Lock S, Wells F, eds. *Fraud and misconduct in scientific research*. London: BMJ Publishing Group, 1993.
11 Mills JL. Data torturing. *N Engl J Med* 1993;329:1196-9.
12 Babbage C. *Reflections on the decline of science in England*. New York: Augustus M Kelley, 1970: 174-83. (Cited in Broad W, Wade N. *Betrayers of the truth*. Oxford: Oxford University Press, 1982: 29-30.)
13 Bailar JC. Bailar's laws of data analysis. *Clin Pharmacol Ther* 1976;20:113-20.
14 Bailar JC. Communicating with a scientific audience. In: Bailar JC, Mosteller F, eds. *Medical uses of statistics*. Waltham, MA: NEJM Books, 1986:325-37.
15 Bland JM, Altman DG, Royston JP. Statisticians in medical schools. *J R Coll Physicians London* 1990;24:85-6.

Science in schools: decline and fall?

A possible shortfall of qualified medical school applicants

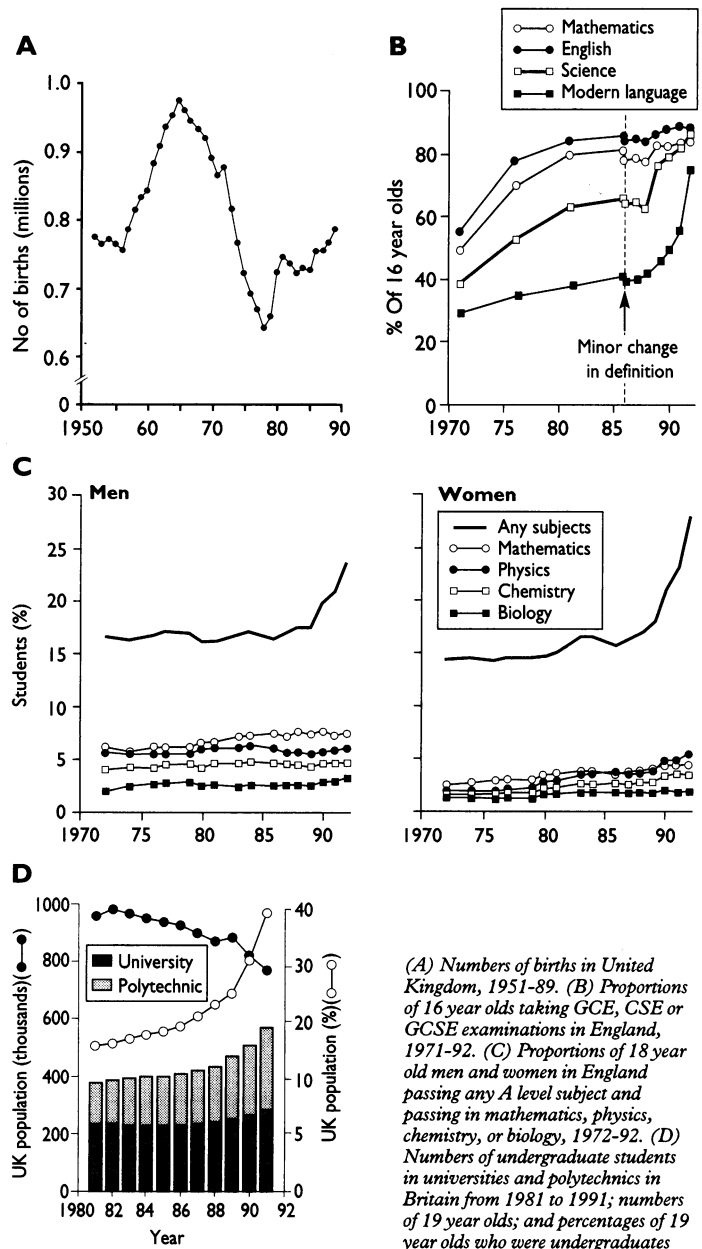
Sciences are learning facts from a book and not thinking for yourself; I wanted to express my own ideas and think for myself.

(A level student quoted in *New Statesman*¹)

The dog days of August are a difficult time: for journalists there is little important news, while for students at school the only news that matters is the results of their general certificate of secondary education (GCSE) and A level examinations. Not surprisingly, the two interests combine in newspaper articles claiming that standards are slipping (or perhaps improving), quality is rising (or perhaps falling), or, as last year, talk of a "decline in science" (*Financial Times*), a "science slump" (*Times Education Supplement*), a "continuing decline in [science] qualifications" (*Nature*), or "science... losing its grip on the syllabus" (*Times*). More recently an article in *New Scientist* headed "Classroom science goes into free fall" quoted John Patten, the education secretary, as saying that there had been a "neo-exponential decline" in students going in to A level science.² Is there a flight from science? And how might it affect medical schools, whose principal import is school leavers with good science A levels?

Although the number of entries for science GCSEs in 1993 was 1.7% lower than in 1992, total entries for GCSEs fell by 4.2%, suggesting that science survived relatively well. Undoubted large falls in entries for biology, physics, and chemistry studied as single subjects were readily compensated for by the increasingly popular combined science courses, which are now the norm. The demographic background to such statistics is four decades of changing birth rates; the rate in 1965 was 53% higher than that in 1978 (figure, A). These diminishing cohorts are now in secondary and higher education, and this year's 3.9% decrease in 16 year olds accounts for the fewer entries for GCSEs. Over the longer term, science qualifications have shown increased popularity, partly because of the change from the general certificate of education and the certificate of secondary education to GCSE (introduced in 1988), so that most 16 year olds take a science subject at GCSE level, on a par with those for English and mathematics (figure, B).

The different picture later suggests that what subjects GCSE students take hardly influences their choice of A level



(A) Numbers of births in United Kingdom, 1951-89. (B) Proportions of 16 year olds taking GCE, GCSE or GCSE examinations in England, 1971-92. (C) Proportions of 18 year old men and women in England passing any A level subject and passing in mathematics, physics, chemistry, or biology, 1972-92. (D) Numbers of undergraduate students in universities and polytechnics in Britain from 1981 to 1991; numbers of 19 year olds; and percentages of 19 year olds who were undergraduates