

TESTING TREATMENTS

Chapter 8, 8.3.1

ALL THE RELEVANT, RELIABLE EVIDENCE

deliberately ignore existing evidence. They design, analyze, and report research to paint their own results for a particular treatment in a favourable light. This is what happened in the 1990s when the manufacturer of the anti-depressant drug Seroxat (paroxetine) withheld important evidence suggesting that, in adolescents, the drug actually increased symptoms that prompted some of these young patients to contemplate suicide as a way of dealing with their depression.⁹

Over-reporting is a problem as well. In a phenomenon known as ‘salami slicing’, researchers take the results from a single trial (the salami) and slice the results into several reports without making clear that the individual reports are not independent studies. In this way, a single ‘positive’ trial can appear in several journals in different articles, thereby introducing a bias.¹⁰ Here again, registering trials at inception with unique identifiers for every study will help to reduce the confusion that can result from this practice.

WHAT CAN HAPPEN IF ALL THE RELEVANT, RELIABLE EVIDENCE IS NOT ASSESSED?

Fair tests of treatments involve reviewing systematically all the relevant, reliable evidence, to see what is already known, whether from animal or other laboratory research, from the healthy volunteers on whom new treatments are sometimes tested, or from previous research involving patients. If this step is overlooked, or done badly, the consequences can be serious – patients in general, as well as participants in research, may suffer and sometimes die unnecessarily, and precious resources both for healthcare and for research will be squandered.

Avoidable harm to patients

Recommended treatments for heart attacks that had appeared in textbooks published over a period of 30 years were compared with evidence that could have been taken into account had the authors systematically reviewed the results of fair tests of treatment reported during that time.¹¹ This comparison showed that the textbook recommendations were often wrong because the authors

SCIENCE IS CUMULATIVE, BUT SCIENTISTS DON'T ACCUMULATE EVIDENCE SCIENTIFICALLY

'Academic researchers have been talking about something called "cumulative meta-analysis" for 25 years: essentially, you run a rolling meta-analysis on a given intervention, and each time a trial is completed, you plug the figures in to get your updated pooled result, to get a feel for where the results are headed, and most usefully, have a good chance of spotting a statistically significant answer as soon as it becomes apparent, without risking lives on further unnecessary research.'

Goldacre B. *Bad Science: How pools of blood trials could save lives.*
The Guardian, 10 May 2008, p16.

had not reviewed the relevant evidence systematically. The impact of this was devastating. In some cases, patients with heart attacks were being deprived of life-saving therapies (for example, clot-busting drugs). In other cases, doctors continued to recommend treatments long after fair tests had shown they were lethal (for example, the use of drugs that reduce heart rhythm abnormalities in patients having heart attacks (see above and Chapter 2, p14-15).

The failure to combine the results of studies in systematic reviews as new evidence becomes available continues to harm patients. Blood substitutes that need no refrigeration or cross-matching are an obviously attractive alternative to real blood for the treatment of haemorrhage. Unfortunately these products increase the risk of heart attacks and death. Furthermore, a systematic review of the randomized trials reported since the late 1990s reveals that their dangers could and should have been recognized several years earlier than they were.¹

Avoidable harm to people participating in research

Failure to assess all relevant, reliable evidence can also result in avoidable harm to people who participate in research. Researchers