

TESTING TREATMENTS

Chapter 8, 8.3.2 TESTING TREATMENTS

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

continue to be commissioned and allowed to do studies that involve withholding treatments known to be effective. For example, long after reliable evidence was available showing that giving antibiotics to patients having bowel surgery reduced their chances of dying from complications of the operation, researchers continued to do comparison studies that involved withholding antibiotics from half the patients participating in controlled trials. The researchers' failure to review systematically what was already known deprived half the participants in their studies of a known beneficial treatment. This serious lapse was evidently overlooked by the funding bodies who financed their research, and by the research ethics committees which reviewed the protocols and failed to challenge the researchers.

It is not only patients requiring treatment who can be put at risk if researchers do not assess systematically what is already known about the effects of the treatments they will be given. Healthy volunteers can be harmed too. The first phase of testing some treatments often involves a very small number of healthy volunteers. In 2006, six young men volunteers at a private research facility in West London were given infusions of a drug that had not previously been used in people. They all suffered life-threatening complications – one of them losing fingers and toes – and their long-term health has been compromised. This tragedy could most probably have been avoided¹³ if a report of a severe reaction to a similar drug had been submitted for publication,¹⁴ and if the researchers had assessed systematically what was already known about the effects of such drugs.¹⁵ Had they done so, they might not have proceeded with their study at all, or if they had decided to go ahead, they might have injected the volunteers one at a time rather than simultaneously; and they could and should have warned the healthy young volunteers about the possible dangers.¹⁶

Wasted resources in healthcare and research

Failure to do systematic reviews of relevant, reliable research evidence does harm even when it is not harming patients and people participating in research. This is because it can result in resources being wasted in healthcare and health research. During