

TESTING TREATMENTS

10 RESEARCH IS GOOD, BAD, AND UNNECESSARY

Chapter 10, 10.2

In the 1990s a group of researchers began exploring, systematically, what treatments had been used for tardive dyskinesia over the preceding 30 years. Writing in 1996, they were rather surprised to have identified about 500 randomized trials involving 90 different drug treatments. Yet none of these trials had produced any useful data. Some of the trials had included too few patients to give any reliable results; in others the treatments had been given so briefly as to be meaningless.¹¹

Members of the same research group went on to publish a comprehensive survey of the content and quality of randomized trials relevant to the treatment of schizophrenia in general. They looked at 2,000 trials and were disappointed in what they found. Over the years, drugs have certainly improved the prospects for people with schizophrenia in some respects. For example, most patients can now live at home or in the community. Yet, even in the 1990s (and still today), most drugs were tested on patients in hospital, so their relevance to outpatient treatment is uncertain. On top of that, the inconsistent way in which outcomes of treatment were assessed was astonishing. The researchers discovered that over 600 treatments – mainly drugs but also psychotherapy, for example – were tested in the trials, yet 640 different scales were used to rate the results and 369 of these were used only once. Comparing outcomes of different trials was therefore severely hampered and the results were virtually uninterpretable by doctors or patients. Among a catalogue of other problems, the researchers identified many studies that were too small or short term to give useful results. And new drug treatments were often compared with inappropriately large doses of a drug that was well known for its side-effects, even when better tolerated treatments were available – an obviously unfair test. The authors of this review concluded that half a century of studies of limited quality, duration, and clinical utility left much scope for well-planned, properly conducted, and competently reported trials.¹²

Epidural analgesia for women in labour

The importance of assessing outcomes that matter to patients is clearly illustrated – in a very negative fashion – by early trials of epidural analgesia given to women for pain relief during labour.

In the 1990s researchers reviewed the experience with controlled trials of epidural versus non-epidural analgesia. They estimated that, despite millions of women having been offered an epidural block over the preceding 20 years, fewer than 600 appeared to have participated in reasonably unbiased comparisons with other forms of pain relief. They identified nine comparison trials that could be confidently analyzed. The comparisons were commonly measured in terms of levels of hormones and other substances believed to reflect stress during labour. Outcomes for the baby were also the focus of some attention. Yet any comparison of the pain reported by the women themselves was absent in all but two of the trials. In other words, those conducting the trials had largely overlooked an outcome that was surely of supreme importance – how effectively a woman’s pain had been relieved.¹³

UNNECESSARY RESEARCH

Respiratory distress in premature babies
Some research falls in between good and bad – it is plainly unnecessary. An example of such research concerns premature babies. When babies are born prematurely their lungs may be underdeveloped, with the risk of life-threatening complications such as respiratory distress syndrome. By the early 1980s there was overwhelming evidence that giving a steroid drug to pregnant women at risk of giving birth prematurely reduced the frequency of respiratory distress syndrome and death in newborn babies. Yet over the ensuing decade trials continued to be done in which steroids were compared with a placebo or no treatment. If the results of earlier trials had been reviewed systematically and combined using meta-analysis (see Chapters 7 and 8), it is unlikely that many of the later trials would have been started – the collective evidence would have shown that there was simply no need. These unnecessary studies therefore denied effective treatment to half the participants in these trials.

Stroke

Another example of unnecessary research, yet again because the results of preceding studies had not been gathered together and