

individual research studies, should be set out in research protocols. Protocols need to make clear what measures researchers will take to reduce biases and the effects of the play of chance during the process of preparing the reviews. These will include specifying which questions about treatments the review will address; the criteria that make studies eligible for inclusion in the review; the ways in which potentially eligible studies will be identified; and the steps that will be taken to minimize biases in selecting studies for inclusion in the review, and for analysing the data.

### **Identifying all the relevant evidence for systematic reviews**

Identifying all the relevant evidence for systematic reviews – irrespective of the language or format of the relevant reports – always presents a substantial challenge, not least because some relevant evidence has not been reported in public. Under-reporting stems principally from researchers not writing up or submitting reports of their research for publication because they were disappointed with the results. And pharmaceutical companies suppress studies that do not favour their products. Journals, too, have tended to show bias when they reject submitted reports because they deem their results insufficiently ‘exciting’.<sup>3</sup>

Biased under-reporting of research is unscientific and unethical, and there is now widespread acceptance that this is a serious problem. In particular, people trying to decide which treatments to use can be misled because studies that have yielded ‘disappointing’ or ‘negative’ results are less likely to be reported than others, whereas studies with exciting results are more likely than others to be ‘over-reported’.

The extent of under-reporting is astonishing: at least half of all clinical trials are never fully reported. This under-reporting of research is biased and applies to large as well as small clinical trials. One of the measures that has been taken to tackle this problem has been to establish arrangements for registering trials at inception, and encouraging researchers to publish the protocols for their studies.<sup>3</sup>

Biased under-reporting of research can even be lethal. To their great credit, some British researchers decided to report in 1993 the results of a clinical trial that had been done thirteen

## MARKETING-BASED MEDICINE

‘Internal documents from the pharmaceutical industry suggest that the publicly available evidence base may not accurately represent the underlying data regarding its products. The industry and its associated medical communication firms state that publications in the medical literature primarily serve marketing interests. Suppression and spinning of negative data and ghostwriting [see Chapter 10, p124-5] have emerged as tools to help manage medical journal publications to best suit product sales, while disease mongering and market segmentation of physicians are also used to efficiently maximize profits. We propose that while evidence-based medicine is a noble ideal, marketing-based medicine is the current reality.’

Spielmanns GI, Parry PI. *From Evidence-based Medicine to Marketing-based Medicine: Evidence from Internal Industry Documents*. *Journal of Bioethical Inquiry* 2010;7(1):13-29. Available online: <http://tinyurl.com/Spielmanns>.

years earlier. It concerned a new drug for reducing heart rhythm abnormalities in patients experiencing heart attacks. Nine patients had died after taking the drug, whereas only one had died in the comparison group. ‘When we carried out our study in 1980,’ they wrote, ‘we thought that the increased death rate in the drug group was an effect of chance... The development of the drug [lorcainide] was abandoned for commercial reasons, and this study was therefore never published; it is now a good example of “publication bias”. The results described here...might have provided an early warning of trouble ahead.’<sup>4</sup> The ‘trouble ahead’ to which they were referring was that, at the peak of their use, drugs similar to the one they had tested were causing tens of thousands of premature deaths every year in the USA alone (see Chapter 2, p14-15).<sup>5</sup>