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Clinical research: for whose benefit?

The way in which new drugs are evaluated before market release is increasingly criticised, for many reasons, including methodological biases, non-publication of trials with negative results, so-called data massaging, and drug regulatory agencies' conflicts of interest. Many of these problems result from the fact that society has delegated the task of assessing the efficacy and safety of new products to the very companies that manufacture them. Drug companies are then in a position to finance and influence study design, clinical researchers and drug regulatory agencies.

We have long been highlighting the fact that premarketing studies regularly fail to provide answers to the concrete questions that concern patients and healthcare professionals. Many other authors agree with this assessment (**a**).

Evaluation disconnected from reality. Many healthcare professionals have found that the new treatments they prescribe are often less effective and less well tolerated than claimed in clinical trial reports. This is mainly due to the fact that trials are conducted under conditions that bear little resemblance to real-world circumstances: there are relatively few trial participants and they are not representative of "real" patients; participants are closely monitored and adhere better to treatment; and there are often no comparisons with other treatment options (1).

Efficacy or "explanatory" trials conducted under tightly controlled conditions are sufficient to obtain marketing authorisation, but pragmatic trials, conducted under real-life conditions, are more relevant to patients' and healthcare professionals' concerns (1).

Trials focus on marketing authorisation, not patient care. Explanatory trials are the most popular trials with drug companies and clinical researchers because they are easier to conduct and less expensive. They meet drug regulatory agencies' requirements by providing simple answers to simple questions: for example, by showing that a new drug has more effect than placebo on a surrogate laboratory marker. This means that drugs are introduced to the market with very limited evaluation of their efficacy and adverse effects in real-world settings (1).

Much remains to be done to ensure that drug research and evaluation start to focus on patients' real needs. But a growing awareness of this problem, combined with the current dearth of innovation, should encourage drug companies and governments to take steps in the right direction.

Prescrire

a- The Canadian Medical Association Journal and the Journal of Clinical Epidemiology published a series of articles on this issue in May 2009, including reference 1.

1- Zwarenstein M and Treweek S "What kind of randomized trials do we need?" *CMAJ* 2009; **180** (10): 998-1000.