

Drug Trial Reports Omit Safety Information

A report in Tuesday's *Journal of the American Medical Association* finds that medical journals devote, on average, a third of a page to safety information--such as potentially dangerous side effects. That's on par with the space typically devoted to contributor names and affiliations, the authors note.

Of seven major categories of drug therapy studied--including drugs for HIV, high blood pressure and heart attacks--the authors were unable to find even one example in which safety reporting could be deemed "satisfactory."

"Adequate reporting of drug safety problems is critical because clinical trials have traditionally been the foundation of high-quality, evidence-based medical practice," said Dr. John Eisenberg, director of the US Agency for Healthcare Research and Quality, which helped to fund the study.

Dr. John P.A. Ioannidis, of Tufts University School of Medicine, and Dr. Joseph Lau of the New England Medical Center examined a total of 192 drug trials, each involving a minimum of 100 patients.

Just 39% of drug trials adequately reported clinical adverse effects of the medications being studied. Only 29% did a good job of reporting the toxicity of a drug revealed through an abnormal lab test result.

And although 75% of trial reports mentioned the number of patients who had to be withdrawn from a study because of a drug's toxicity, specific reasons for the withdrawals were mentioned only 46% of the time.

Most high-quality trials collect enormous amounts of safety and adverse effects data, Ioannidis and Lau note. "Yet, the selective filtering of all these data into a quarter of a page can hardly be adequate," they write.