Selective reporting of antidepressant trials exaggerates drug effectiveness

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Selective publication in reporting results of antidepressant trials exaggerates the effectiveness of the drugs, according to a report in the January 17 issue of the *New England Journal of Medicine*. The report's primary author is Erick Turner, M.D., assistant professor of psychiatry, physiology and phamacology at Oregon Health & Science University (OHSU) and Medical Director of the Portland Veterans Affairs Medical Center's Mood Disorders Program.

Turner and his colleagues examined reviews from the Food and Drug Administration (FDA) for trials of 12 widely prescribed antidepressant drugs approved between 1981 and 2004, involving 12,564 patients. They also conducted a systematic literature search to identify whether results of these studies had been published in medical journals. For trials that had been published, they compared the published version of the results with the FDA version of the results.

Whether and how the studies were published depended on how they turned out, Turner's team found. According to the published literature, nearly all studies conducted (94 percent) had positive treatment results, but FDA data showed that in fact only about half (51 percent) of the studies were positive. Positive studies, with one exception, were all published. Most studies (33 out of 36) that were not positive either were not published or were published as if they were positive, in conflict with the FDA conclusions. These 33 studies involved 5,212 patients.

"Selective publication can lead doctors and patients to believe drugs are

more effective than they really are, which can influence prescribing decisions, said Turner. He also cautioned that the surprisingly large number of negative studies does not mean that antidepressants are ineffective. His team found that each drug, when all its studies were combined using a statistical technique called meta-analysis, was superior to treatment with a placebo (sugar pill). On the other hand, this analysis also showed that each drug, based on the FDA data, was less effective than it would appear from the published literature.

Turner said that he and his colleagues don't know whether the bias resulted from a failure of authors and sponsors to submit manuscripts, from decisions by journal editors and reviewers not to publish, or both. "Regardless, doctors and patients must have access to evidence that is complete and unbiased when they are weighing the risks and benefits of treatment," he emphasized.

Source: Oregon Health & Science University