

## Medical journals get tough on drug companies

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Some of the world's leading medical journals say they will no longer publish results of clinical trials that have not been registered publicly, a move designed to prevent drug companies from hiding unfavourable results.

"Honest reporting begins with revealing the existence of all clinical studies, even those that reflect unfavourably on a research sponsor's product," the International Committee of Medical Editors wrote in a commentary that will appear in 11 prestigious journals.

"Unfortunately, selective reporting of trials does occur, and it distorts the body of evidence available for clinical decision-making."

The move is important because physicians rely heavily on articles in these journals when deciding what drugs to prescribe to patients.

The statement from the editors of the *New England Journal of Medicine*, *Journal of the American Medical Association*, the *Lancet*, and the *Canadian Medical Association Journal*, among others, coincides with hearings in Washington today about a lack of disclosure from trials of the safety of antidepressants in children and adolescents.

The revelation that some antidepressants may actually increase suicidal thoughts in younger users, information that was withheld by drug makers, has caused a fury in the international medical research community and outraged parents of children who were prescribed the drugs.

U.S. lawmakers are expected to introduce legislation today that would require all drug trials involving human subjects to be registered in a public database before they are allowed to proceed.

The Canadian Institutes for Health Research announced last month that it will no longer fund clinical trials unless they are duly registered, a policy it said was designed to "support the drive for greater openness of information."

A clinical trial is a research study using human volunteers designed to answer a specific health question such as: "Does anastrozole delay the recurrence of breast cancer in postmenopausal women?"

Clinical trials are considered the gold standard of research.

But sometimes research produces unclear results or findings that are the opposite of what the research sponsor expected, and that news could potentially cost a company millions of dollars in lost sales.

In their commentary, the journal editors said researchers and the companies that sponsor them have an obligation to conduct research ethically and report it honestly, regardless of the financial fallout. They said this is particularly true because the research depends on altruistic volunteers.

The editors said that publishing only positive results paints too rosy a picture and misleads consumers and prescribing physicians about the true safety and effectiveness of drugs.

John Hoey, editor of the *Canadian Medical Association Journal*, said the position taken by the editors is an unusual one because it will not really affect their publications directly, rather, it is more a matter of principle.

"Why should we care about stuff that's unpublished?" he asked rhetorically.

"Our feeling is that by doing this we can do some public good."

In addition to its demand that clinical trials be registered before human subjects are enlisted, the editors laid out a number of criteria for an "acceptable" registry, including that the goals of the research be stated clearly, that primary and secondary outcomes be revealed and that the database be electronically searchable and publicly accessible at no charge.

As part of the new policy, trials must register at or before the onset of patient enrolment.

What this means is that the researchers and their sponsors are making a commitment to reveal the findings of their trials -- long before the results are in and regardless of whether they are positive or negative.

While various registries have sprung up -- including one announced earlier this week by the drug manufacturers themselves -- the editors said only one meets their criteria: <http://www.clinicaltrials.gov/>, which is sponsored by the U.S. National Library of Medicine.

Although only 11 journal editors formulated the statement, other medical journals are expected to widely adopt the approach.

The signatories acknowledge that drug companies could try and sidestep the registry by getting research published elsewhere, but they argued that many researchers would be reluctant to sign contracts that might preclude them from being published in leading journals.