Major medical journals unite in call for Clinical Trials Registration

New Policy: Studies Must Be Registered in Free, Searchable Databases

The editors of *Transplantation*, the official journal of The Transplantation Society, have announced that *Transplantation* will join with other leading kidney journals and the major general journals—such as *New England Journal of Medicine* and *The Lancet*—in establishing a policy that clinical research studies involving trials will only be considered for publication if they have been submitted to a free, electronically searchable clinical trial register.

The new policy is outlined in an editorial to be published in the April 15 issue of the *Transplantation.* The policy has also been endorsed by five other major kidney and transplantation journals: *Journal of the American Society of Nephrology; Nephrology, Dialysis, Transplantation; The American Journal of Transplantation; The American Journal of Kidney Diseases;* and *Kidney International.*

By requiring advance registration of clinical trials, the editors seek to ensure that full information on these studies will be freely available to the general public. The policy is intended to address the problem of "selective publication"—studies yielding negative results are often not submitted for publication, and thus not included in the body of available research evidence on a given treatment.

Unpublished studies—especially those sponsored by pharmaceutical companies—have been at the heart of recent controversies over unreported adverse effects of medications. A prime example is the debate over the risk of suicide by young patients taking certain antidepressant drugs. The danger went unrecognized until unpublished studies were included in risk-benefit analyses for these drugs.

Under the new policy, all studies to be submitted for publication in *Transplantation* or the other kidney/transplantation journals must be listed in a public trials registry. In the future, researchers will have to register their studies before they start enrolling patients; studies that are already underway or will be starting this year have until April, 2006 to register. The policy does not apply to more basic initial studies, such as those designed to assess the pharmacology or toxic effects of a medication before it is entered into a clinical trial.

The editors do not stipulate any specific trial registry, but the registries must be available to the public without charge and electronically searchable, among other requirements. A handful of such registries have already been established, such as the U.S. National Library of Medicine's registry, accessible on the Internet at www.clinicaltrials.gov. Other eligible registries are listed in the April 15 editorial.

In announcing the new policy, Professor Peter Morris of *Transplantation* and his fellow editors write, "Medical research can be seriously compromised by the selective publication of clinical trial results. Indeed failure to report negative results is scientifically fraudulent. Therefore, it is imperative that information regarding all clinical trials should be available to the general public and the profession."

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