JOHNSHOPKINS



Department of Biostatistics Department of Epidemiology Department of International Health Department of Medicine Department of Ophthalmology Oncology Center 6 February 2015

Memorandum

To: Trialists

Fr: Curtis Meinert

Re: Toward a better system of registration?

The International Committee of Journal Editors (ICJME),* in a September 2004 statement, announced that

ICMJE member journals will require, as a condition of consideration for publication, registration in a public trials registry. Trials must register at or before the onset of patient enrollment. This policy applies to any clinical trial starting enrollment after July 1, 2005. For trials that began enrollment prior to this date, the ICMJE member journals will require registration by September 13, 2005, before considering the trial for publication.

The push for registration was driven by the ICJME's concern that "sponsors or investigators conceal the presence of selected trials" (depending on the nature and direction of results). The "fix" was to require registration before trials are started. One can question the wisdom of the fix because it prevents one type of selective reporting while creating a different one – whether trials are registered.

Fortunately the policy is not monolithic. Of the 3,157 publications indexed in PubMed as "randomized controlled trial" and published between 1 January 2014 and 30 June 2014, only 22% reported registration numbers. Fifty-five percent of the 1,097 publications indexed as multicenter study and randomized controlled trial contained registration numbers, but that number is skewed by ICJME journals. Most of the trials in those journal are randomized and multicenter.

The system we need is one where <u>all</u> editors of medical journals (not just the International Committee of Medical Journal Editors) indicate whether the trials they published are registered. Under the system they would provide registration numbers or indicate "Not registered" in abstracts. That practice would save those interested in the information contained in registrations from searching for nonexistent registrations.

Trialists and the agencies funding trials are pressured to register. Who is pressuring journal editors to do what they need to do make registration serve its purpose?

* The ICMJE, originally known as the Vancouver Group (after the location of its first meeting), consisted of editors from 12 medical journals. Now it consists of editors from 15 journals.