



Department of Epidemiology
Johns Hopkins Bloomberg School of Public Health
415 N. Washington Street, 2nd Floor
Baltimore, Maryland 21231

9 January 2019

Memorandum

To: Trialists

Fr: Curtis Meinert

Re: Miss rates for editors and indexers in regard to registration numbers for trials

The National Library of Medicine indexes publication by type, one type being “randomized controlled trial” defined as

A work that reports on a clinical trial that involves at least one test treatment and one control treatment, concurrent enrollment and follow-up of the test- and control-treated groups, and in which the treatments to be administered are selected by a random process, such as the use of a random-numbers table.

It also indexes registration numbers (referred to as SIDs in the lexicon of the NLM). The NLM started indexing ClinicalTrials.gov numbers in 2005. It expanded indexing to include ISRCTN numbers in 2006. By 2018 it indexes 20 different registration sites, including all sites represented on the WHO registration platform.

A previous memo (dated 29 November 2018) listed the ten journals with the most 2016 publications indexed in PubMed to the publication type [RZT]. The journal **Trials** had the most (475) and **PLOS One** was second (410 publications). **PLOS One** had the largest number of publications not having indexed registration numbers (239 publications); 58% of the **PLOS One** publications compared to just 2% of **Trials** publications.

	Journal	Total	No. with indexed registration no.	No. without indexed registration no.
1	Trials	475	465	10
2	PLOS One	410	171	239
3	BMJ Open	285	235	50
4	Medicine (Baltimore)	187	19	168
5	Contemp Clin Trials	148	50	98
6	BMC Pub Health	135	113	22
7	NEJM	134	133	1
8	Am J Clin Nur	127	111	16
9	Lancet	123	109	14
10	Int J Cardiol	117	13	104
		2,141	1,419	722

The editor of **PLOS One**, when queried about the results for his journal questioned the observation. His skepticism led to a more extensive review of editor and indexer practices in dealing with registration numbers.

Assuming all publications indexed to the publication type [RZT] are to be registered, an “editor miss” is a publication indexed by NLM as a [RZT] that does not have a posted registration number. An “indexer miss” is an [RZT] indexed publication with a registration number posted but not indexed.

The “miss rates” in the table below are based on inspections of abstracts of the 2,141 publications represented in the table.

Editor and indexer miss rates for registration numbers

	Col A	Col B	Col C	Col D	Col E	Col F	Col G	Col H
	Journal	Publications indexed [RZT]	Publications with registration number posted [*]	Publications absent posted registration number; Editor miss count	Publications with registration number posted not indexed. Indexer miss count	Col D/Col B Editor miss rate	Col E/Col B Indexer miss rate	(Col D + Col E)/ Col B Combined miss rate
1	Trials	475	465	3	7	0.01	0.01	0.02
2	PLOS One	410	171	198	41	0.48	0.10	0.58
3	BMJ Open	285	235	14	36	0.05	0.13	0.18
4	Med (Baltimore)	187	13	172	2	0.92	0.01	0.93
5	Contemp Clin Trials	148	23	124	1	0.84	0.01	0.84
6	BMC Pub Health	135	113	21	1	0.16	0.01	0.16
7	NEJM	134	133	1	0	0.01	0.00	0.01
8	Am J Clin Nur	127	111	4	12	0.03	0.09	0.13
9	Lancet	123	109	2	12	0.02	0.10	0.11
10	Int J Cardiol	117	13	101	3	0.86	0.03	0.89
		2,141	1,386	640	115	0.30	0.05	0.35

* Counted as registered even if not a recognized site

The combined editor and indexer miss rates range from 0.01 for the NEJM to 0.89 for the Int J Cardiol. The majority of misses are due to editors failing to report registration numbers in publications indexed as [RZT]s. Editor misses account for 85% of the misses.

The ICMJE specifies that registration numbers are to be posted at the end of abstracts. For the most part, editors for the ten journals covered here posted registration numbers in abstracts, but not necessarily where recommended. For example, Lancet, one of the signatory journals to the recommendation posts numbers in the middle of abstracts (at the end of “Methods” and just before “Findings”).

The numbers can be anywhere in **PLOS One** papers. Of the 239 publications not indexed as having registration numbers, downloads of the papers and inspections identified 115 that actually had numbers listed but not indexed. Of these, numbers were posted in the bodies of 61 manuscripts and in the abstracts of 54 of the other 115. The split does not provide evidence that misses in indexing are related to where numbers are posted in manuscripts.

One of the problems for editors is the disconnect with indexers. Editors have no way of knowing whether the paper they are about to publish will be indexed as an [RZT]. If it is and they do not post a number it will be an “editor miss”. Indeed, I know from reading abstracts of papers for this piece that indexers are generous in applying the publication type [RZT] to papers. A fair number are comparative and prospective but not randomized. The disconnect can be reduced if editors follow the duck rule for trials. If the paper is about a comparative study and involves prospective followup, it is a trial and

should be reported with a registration number or readers should be informed the study has not been registered.