

JOINT EVENT

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Have treatment studies of depression become even less generalizable? applying the inclusion and exclusion criteria in placebo controlled antidepressant efficacy trials published over 20 years to a clinical sample**Mark Zimmerman and Caroline Balling**

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Introduction: We previously conducted a review of the psychiatric inclusion/exclusion criteria in placebo-controlled AETs published from January, 1995 through December, 2014. We compared the criteria of studies published during the past 5 years (2010-2014) to those of the prior 15 years (1995-2009) and found that the inclusion/exclusion criteria for AETs narrowed in the studies of the more recent five years thereby suggesting that AETs may be even less generalizable than they were previously. In this presentation we apply the criteria used in these studies to a large sample of depressed outpatients to examine the actual impact of the change on generalizability.

Methods: One thousand two hundred seventy-one patients with a principal diagnosis of major depressive disorder were interviewed with semi-structured interviews. The psychiatric inclusion/exclusion criteria of 122 placebo-controlled AETs were applied to the patients.

Results: Across all studies, the percentage of patients that would have been excluded ranged from 44.4% to 99.4% (mean=86.0%). The percentage of patients that would have been excluded was significantly greater in the studies published in 2010-2014 compared to the studies published during the prior 15 years (93.6% vs. 83.9%, $p<.001$).

Discussion: The results expand prior findings that only a minority of depressed patients seen in clinical practice are likely to be eligible for most AETs, thereby raising questions about the generalizability of AETs to patients treated in the real world. Moreover, generalizability was significantly lower in more recently conducted studies.

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