

Study raises concerns about reporting of noninferiority trials

March 17 2015

An examination of the reporting of noninferiority clinical trials raises questions about the adequacy of their registration and results reporting within publicly accessible trial registries, according to a study in the March 17 issue of *JAMA*.

Noninferiority [clinical trials](#) are designed to determine whether an intervention is not inferior to a comparator by more than a prespecified difference (known as the noninferiority margin). Selection of an appropriate margin is fundamental to noninferiority trial validity, yet a point of frequent ambiguity. Given the increasing use of noninferiority trial designs, maintaining high standards for conduct and reporting is a priority, according to background information in the article.

Joseph S. Ross, M.D., M.H.S., of the Yale University School of Medicine, New Haven, Conn., and colleagues examined registration records and results of noninferiority clinical trials posted on ClinicalTrials.gov, as well as their corresponding publications, for information about the noninferiority margin and [statistical analyses](#). Because ClinicalTrials.gov does not require registration of noninferiority-specific information, the authors searched MEDLINE for noninferiority trials published between January 2012 and June 2014, then selected publications reporting primary analyses of noninferiority trials indexed with a ClinicalTrials.gov identifier. The researchers recorded details on trial design (including specification and justification of the noninferiority margin) and results (including reporting of noninferiority statistical analyses) from both ClinicalTrials.gov and corresponding

publications.

The authors identified and characterized 344 unique trials registered on ClinicalTrials.gov, published in 338 articles (6 described multiple trials) that reported primary results of noninferiority [trials](#). All publications described noninferiority designs and nearly all (98.8 percent) provided noninferiority margins. However, any justification for choosing margins was provided for only 28 percent. On ClinicalTrials.gov, approximately onequarter described noninferiority designs, among which 15 (4.4 percent of total) specified noninferiority margins.

Nearly all publications reported noninferiority analyses and results (99.4 percent). On ClinicalTrials.gov, 38 percent had posted summary results, among which 76 (22 percent of total) reported that noninferiority analyses were performed and provided appropriate confidence intervals or P values to interpret results.

"Our findings raise concerns about the adequacy of noninferiority trial registration and results reporting within publicly accessible trial registries and highlight the need for continued efforts to improve its quality," the authors write.

They add that even though ClinicalTrials.gov does not provide specific [registration](#) data elements for specifying noninferiority trial designs, it does provide specific elements for reporting noninferiority results.

"Nevertheless, modifications may improve reporting and temper the possibility of post hoc distortion of design and margins, facilitating transparency and accountability for noninferiority trial conduct."

More information: [DOI: 10.1001/jama.2015.1697](https://doi.org/10.1001/jama.2015.1697)

Provided by The JAMA Network Journals

Citation: Study raises concerns about reporting of noninferiority trials (2015, March 17)
retrieved 27 April 2024 from <https://medicalxpress.com/news/2015-03-noninferiority-trials.html>

This document is subject to copyright. Apart from any fair dealing for the purpose of private study or research, no part may be reproduced without the written permission. The content is provided for information purposes only.