Randomized Controlled Trials (RCTs) are the gold standard in the assessment of a treatment effect. The magnitude of this effect can be presented in various ways, eg, relative risk reduction (RRR), absolute risk reduction (ARR), and odds ratio (OR). In 1988, Laupacis et al. reported the number needed to treat (NNT), an expression of the number of patients who must be treated to prevent one adverse event. Mathematically, NNT equals the reciprocal of the ARR. Reporting this value provides readers with additional information to help them decide whether a treatment should be used. Failing to report NNT may influence the interpretation of study results. For example, reporting RRR alone may lead a reader to believe that a treatment effect is larger than it really is. We examined the frequency of explicit reporting of NNT and ARR in RCTs.

**METHODS**

Five frequently cited journals were investigated: *Annals of Internal Medicine*, *BMJ*, *JAMA*, *The Lancet*, and the *New England Journal of Medicine*. For each journal, 4 years were assessed: 1989, 1992, 1995, and 1998. The index year was designated 1989 because it represented 1 year after publication on NNT by Laupacis et al. Three-year intervals were selected to obtain a representative sample to observe for changes over time. All issues of each journal were manually reviewed for the specific years of interest. Eligible articles included studies that reported a randomization process, presented binary outcome or survival data, and reported a statistically significant treatment effect. All eligible articles were reviewed independently by 2 of the authors. A data collection form was used to abstract the following information from each article: condition investigated, event being treated or prevented, intervention, study results, and reporting methods (relative risk reduction, NNT, and ARR).

**RESULTS**

There was complete agreement between the 2 reviewers. The summary of findings and journal-specific results is presented in the Table. Five hundred sixty-four articles met the criteria for a randomized trial. Of these, 359 met the additional inclusion criteria. The NNT was reported in 8 articles, and ARR was reported in 18. All 8 articles reporting NNT also presented ARR. Six of the 8 studies reporting NNT and 10 of the 18 reporting ARR were from 1998.

**COMMENT**

The best evidence on the efficacy of medical interventions comes from well-conducted RCTs, but unless the results of such trials are reported adequately, assessing that information is difficult. The methods by which data are displayed can influence the interpretation of the study results. The widespread practice of stressing important findings from RCTs is larger than it really is. We examined the frequency of explicit reporting of the number needed to treat (NNT) and the absolute risk reduction (ARR) in RCTs.
in terms of RRRs may potentially mislead the reader. The NNT and ARR express efficacy by incorporating the baseline risk without therapy and the risk reduction with therapy. Also, NNT allows physicians to understand how much effort is needed to prevent one event, thus allowing comparisons with other disorders.

Despite NNT’s potential, there have been concerns expressed about its limitations. Cook and Sackett note that NNT presents a problem when the results of an RCT with patients at one baseline risk are applied to a particular patient at a different risk. Chatellier et al express concern on extrapolating NNT to time points not considered in trials.

There have been ongoing efforts to improve the quality of reporting results of RCTs, including the Consolidated Standards of Reporting Trials (CONSORT) statement, first published in 1996. A subsequent revision of the CONSORT statement encouraged reporting of absolute values and NNT. Although the use of CONSORT improves the quality of reporting in some areas, the results of our study raise concerns, specifically, that NNT and ARR are underused in the medical literature. These results are consistent with those of similar studies showing that inadequate description of randomization and participant flow are common. Junker described the adherence to published standards of reporting on an 18-item scale; the mean score among 121 reports was 8.4. The results of our study and others suggest the need for additional measures to ensure compliance with reporting standards. These measures should continue to improve the reporting of an RCT and enable readers to better interpret the results.

### REFERENCES