

Urology treatment studies show increased reporting of harmful effects

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In recent years, clinical trial reports in major urology journals have been more likely to include data on harmful effects of treatments, [reports a study](#) in the January issue of *The Journal of Urology*.

"Our analysis finds a marked increase in reporting of [potential harms](#) in randomized treatment trials published in top-ranked [urology](#) journals," comments lead author Reece M. Anderson, MPH, Medical Student Researcher at Oklahoma State University Center for Health Sciences, Tulsa. "This information will help to improve informed decision-making about urology treatments, and contribute to improving the quality of urology research."

Urology RCTs are meeting more criteria for harms reporting

Randomized controlled trials (RCTs) provide the highest quality of evidence for evaluating [medical treatments](#). In addition to evidence of treatment effectiveness, RCTs should include a "balanced, transparent, and unbiased appraisal" of any harmful effects, according to the authors.

However, in urology as in other specialties, published studies often fail to provide adequate data on harms. In 2004, the CONSORT group created a "[harms-specific reporting guideline](#)," with the aim of improving transparency of RCTs. A 2010 paper in *The Journal of Urology* found "[significant deficiencies](#)" in reporting of adverse effects in urology treatments.

Has reporting of harms increased in more recent years? To find out, Mr. Anderson and colleagues analyzed 132 papers published in four journals—*The Journal of Urology*, *Urology*, *European Urology*, and *BJU International*—in 2012 or 2020.

Following a standardized method, the researchers evaluated how well the studies followed the CONSORT harms reporting guidelines. Harms were defined as "any undesirable consequences" of treatment, including adverse events, side effects, complications, toxicity, or other conditions

interfering with [patient safety](#) or satisfaction.

During the period studied, reporting of harms in urology RCTs increased significantly. The median number of harms criteria addressed increased from 5.3 in papers published in 2012 to 7.2 in 2020. Papers published in 2020 reported more than three-fourths of items suggested by the CONSORT guidelines. That contrasts with the study from 2010, when only about one-third of items were addressed.

More progress needed to meet 'standards of transparency and accuracy'

Improvements in the methods used to evaluate harmful effects included which harms were assessed, when the information was collected, and how the harms were attributed to the study treatments. Results criteria improved as well, including gains in reporting the reasons for patient withdrawals, the effect size of the reported harms, and the distinction between serious and minor harms.

But while the results show "marked improvement in completeness of reporting, key deficits still exist," the researchers write. They suggest steps that researchers and [medical journals](#) can take toward further improvement, including checklists addressing each of the CONSORT harms criteria.

"Complete reporting of harms is crucial for ensuring that readers have a comprehensive understanding of the safety and effectiveness of interventions," Mr. Anderson and co-authors conclude. They emphasize the need "for ongoing efforts to ensure that harms reporting meets the highest standards of transparency and accuracy."

More information: Reece M. Anderson et al, Reporting of Harms in

Randomized Controlled Trials Published in Urology Journals: An Updated Analysis, *Journal of Urology* (2023). DOI: [10.1097/JU.00000000000003740](https://doi.org/10.1097/JU.00000000000003740)

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