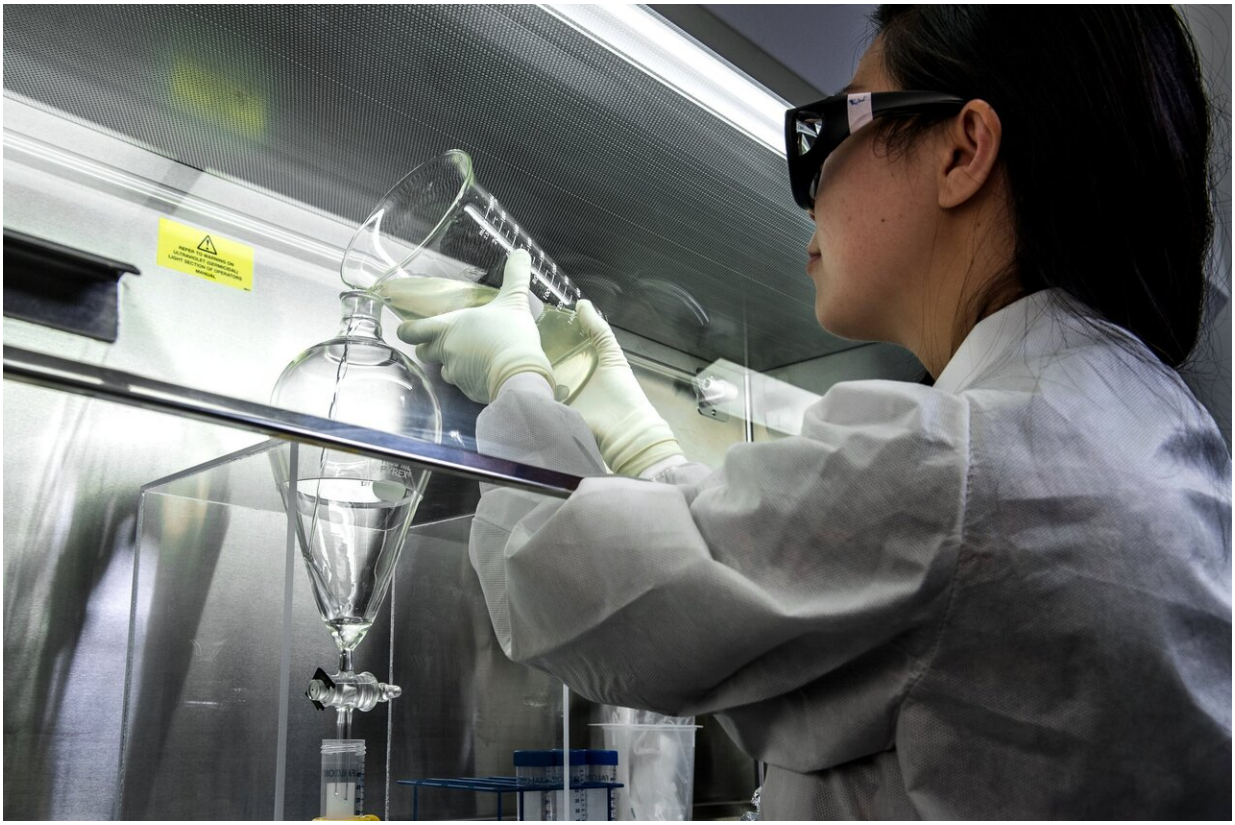
New research raises concerns about clinical trial bias from undisclosed censoring

December 15 2021



Credit: Unsplash/CC0 Public Domain

New research in the December 2021 issue of *JNCCN—Journal of the National Comprehensive Cancer Network* found that only 59% of oncology clinical trials studied provided adequately-defined rules for

censoring. The researchers examined published randomized control trials supporting FDA approval for treatments for solid tumors from January 2015 through December 2019—and found that for 33 out of 81 studies, it was not clear in the publication why or how patients were being censored.

Censoring is defined in this context as the practice of removing patients from follow-up before experiencing the outcome of interest; for instance, if the main outcome of a cancer treatment trial is survival and the patient experiences a heart attack and withdraws from the trial, they may no longer be followed-up. If the proportion of patients who are censored is not evenly balanced between comparison groups, this can introduce bias and makes it difficult to interpret the results of trials.

"We hope that our findings will prompt investigators and journals to report early drug discontinuation, withdrawal of consent, loss to follow-up, and censoring more transparently in trial publications. This would allow patients and clinicians to make more informed decisions regarding the potential benefits of a treatment," said lead researcher Brooke E. Wilson, MBBS, MSc, University of Toronto. "Regulatory authorities and journals can play a leadership role in mandating improved transparency and ensuring that censoring data be made publicly available."

The authors compiled a list of goals and recommendations to improve transparency and reporting in clinical trials. Those goals include:

- Minimize the chance of post-randomization bias
- Improve transparency regarding censoring methods in oncology trials
- Explore the impact of censoring on trial results
- Improve the handling of transparency of missing outcome data in trial results
- Acknowledge the potential impact of censoring on the

interpretation of results
- Provide transparent information regarding early drug discontinuation and withdrawal of consent or loss to follow-up

"In trials with survival outcomes, it's important to clearly and carefully define censoring," commented Elizabeth A. Handorf, Ph.D., Associate Research Professor, Fox Chase Cancer Center, who was not involved in this research. "It's possible that different ways of defining or handling censoring could change the results. It's concerning that so few studies presented sensitivity analyses, as this is the best way for the reader to understand the potential impact of the study's definitions and assumptions. I was surprised to see that 54 studies had a planned sensitivity analysis for censoring rules but only 3 published the results. Even if a sensitivity analysis shows no difference, those results are useful to include."

More information: Brooke E. Wilson et al, Quantifying Withdrawal of Consent, Loss to Follow-Up, Early Drug Discontinuation, and Censoring in Oncology Trials, *Journal of the National Comprehensive Cancer Network* (2021). DOI: 10.6004/jnccn.2021.7015

Provided by National Comprehensive Cancer Network