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Access to these tools can be found on the library's website, and individual eBooks are searchable in the library's catalog with links for access to the appropriate McGraw-Hill collection.

For more information, please contact the library at RML-Help@mdanderson.org, through the chat service available on our site, or by calling 713-792-2729 Monday through Friday, 8 AM to 6 PM.

Best Practices for Reporting Outcomes and Harms

A complete understanding of the risks and benefits of treatments is crucial to clinical decision-making, both for physicians and patients. This understanding, in turn, relies on accurate and clear reporting of outcomes and harms by researchers.

Medical articles commonly use vague or oversimplified language to describe treatments and adverse events, especially in the abstracts and conclusions. Such language, which is sometimes referred to as *subjective minimizing language*, can obscure the interpretation of a study's results, making it difficult for physicians and patients to understand a treatment's potential effects and make fully informed recommendations and decisions. This use of "generic or vague statements" is considered a poor reporting practice, according to the original CONSORT Harms extension guidelines.

Subjective terms are based on opinions, emotions, or feelings rather than on facts. For example, physicians and patients may have different opinions on whether an adverse event is *acceptable* or *tolerable*, and patients' opinions may differ from one to another—one patient might consider a few episodes of diarrhea a day to be *tolerable*, while another might not. Similarly, whether a toxicity profile is considered *favorable* can vary from patient to patient. Subjective terms may also be ambiguous or have unclear definitions. For example, it may be unclear what threshold or measurement was used to determine that a new treatment approach was *feasible*.

Minimizing terms understate the severity of an effect or downplay the risks. In the 2022 CONSORT Harms extension guidelines update, the authors note that the word *safety* can be misleading and can "diminish the importance of harms or imply the absence of harms". Similarly, it would be inaccurate for a trial to describe a treatment's adverse events as *manageable* in the abstract when five patients in the intervention arm died from drug toxicities. No treatment can truly be considered *manageable* or *safe* if it results in hospitalization or death.

When writing for the scientific literature, it is important to report only complete and objective data, including laboratory findings, patient outcomes (e.g., survival, hospitalization, or treatment discontinuation), the incidence and relative risks of adverse events, the use of interventions, and any relevant statistical data. For example, instead of writing, "The aromatase inhibitor letrozole has been shown to be well tolerated and effective in patients with early-stage breast cancer", write "The aromatase inhibitor letrozole resulted in a 5-year disease-free survival rate of 95% compared with 91% for placebo; 10% of patients experienced bone-related toxicities." If terms such as *safe* or *tolerable* are used, specific contexts and strict definitions and cut-off values should be provided (e.g., "The regimen was considered safe if no grade ≥3 adverse events were reported"). It is also important to adhere to all relevant reporting guidelines, including the CONSORT Harms extension guidelines.

The timing, frequency, and duration of adverse events should also be reported, as for some patients, they can be even more important than the risk or incidence. Chronic headaches for a week and a single, transient headache might be reported together in a table as "headache," but they have very different effects on patients' quality of life. Similarly, low-grade fatigue can be cumulatively disabling if it is chronic.

Patient-reported outcomes (PROs) are an important part of adverse event reporting. Often assessed in real time, PROs are designed to provide patients' personal perspectives on symptoms, physical and social functioning, mental and emotional health, health-related quality of life, and treatment adherence and are thus vital to patient-centered care. For more information on including PROs in your research, visit Guidelines for Inclusion of Patient-Reported Outcomes in Clinical Trial Protocols: The SPIRIT-PRO Extension or MD Anderson's Patient Mosaic.

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"Adjust" or "Adjust for"? A Confounding Consideration

In statistics, it's common to speak of confounding variables and the ways of removing their influence so that a relationship between two things can be studied in isolation. This step is sometimes referred to as an *adjustment*. The Britannica Dictionary includes this definition of *adjust*: "to make an amount or number more exact by considering other information — usually + *for*."

In these examples, which wording is preferred?

Option 1: We *adjusted* covariates including age, sex, and treatment.
Option 2: We *adjusted for* covariates including age, sex, and treatment.

Both of these phrasings might be seen in the literature, but *adjusted for* (covariates) is more common and precise. *Adjust for* is preferred when immediately followed by a variable or variables whose influence is being accounted for, i.e., when the object of *adjust for* is a confounder or confounders.

However, if you are referring to a set of values that are themselves altered to remove the influence of confounders, then you would say that they are adjusted, without necessarily including *for*. In short, you *adjust* the main variables being studied, while you *adjust for* confounders. Here are more examples of the acceptable uses of these and similar terms:

Unadjusted and *adjusted* results were both calculated.
The positive findings were no longer detectable in the *adjusted* Cox proportional hazards model.
We *adjusted* home values *for* inflation.
We *adjusted* the hazard ratios *for* known confounding variables.
The regression analysis was *controlled for* disease stage.