Use of medical terminologies to describe adverse event terms in ClinicalTrials.gov

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Objective

To describe type and variability of medical terminology used for adverse event terms in ClinicalTrials.gov in context of mandates by the Food and Drug Administration Amendments Act of 1997 to promote transparency surrounding reporting of trial data.

Study Design and Setting

Cross-sectional study on safety and efficacy trials in ClinicalTrials.gov for common drugs: antidepressants, analgesics or anesthetics, antidepressants, anti-allergics, anti-infectives, enzyme inhibitors, and anti-inflammatory, antineoplastic, hypoglycemic, neuromuscular agents.

Methods

Registered and completed clinical trials with adverse events between 2009 and 2012. We chose trials of 10 drug categories from safety and efficacy trials. We excluded trials without drug intervention or adverse events.

Results

- Out of 93 trials that studied drugs, pain was most studied (n = 5, 5.4%), followed by major depressive disorder (n = 4, 4.3%).
- Most trials were randomized (n = 63, 67.7%).
- MedDRA was most commonly used (n = 30, 32.3% and n = 45, 48.44%) dictionary for serious and other adverse events (SAEs and OAEs), respectively.
- Predominantly, 67 (72%) trials reported OAEs, whereas 42 (45.2%) reported SAEs.
- Majority (n = 51, 54.8%) of drugs were an FDA indication.
- Omitted medical terminology sources were 10 (10.8%) for trials with SAEs and 18 (19.4%) for OAEs.
- Of 236 lay terms for both SAEs and OAEs, same lay term defined up to 3 different adverse events in 11 (11.8%) and 69 (74.2%) trials, respectively.

Conclusion

- MedDRA was predominantly used to define adverse events from trials.
- Many studies failed to provide a source dictionary.
- Without a ClinicalTrials.gov requirement for a standard dictionary, there may be a reduction in comparability of adverse events across studies.
- Administrators at ClinicalTrials.gov may consider the peremptory use of MedDRA or lay terms.

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