

Under-reporting of Adverse Drug Effects in Clinical Research



Reporting of adverse drug effects (ADE) represents one of the very crucial aspects in [clinical research](#). Appropriate documentation and sufficient information about any such effect or reaction can make a huge difference in terms of patients' safety and quality of pharmaceuticals which have been tested, manufactured and approved for general consumption. Being reported in online medical articles and other recourses, adverse events (or side effects which are regularly collected in randomized clinical trials) can help caregivers, practitioners, patients, reviewers and researchers understand the benefits and risks of new treatments. However, according to a number of surveys carried out in the last couple of years, the reporting rates are low due to too many cases of unreported ADEs.

People involved in the field of research sometimes may not realize how crucial reporting practices are. In consequence, they omit details or specifications in study papers published online. In other words, what researchers decide to either accidentally or deliberately conceal, results in physicians' inability to proceed with, evaluate or plan any future treatment methods in the most accurate way. In this sense, inadequate ADE reports are the reason why practitioners cannot signal critical safety issues and other discrepancies. As a result, no changes can be made as to how a medical product is used or marketed. What's even more important, incomplete reporting of adverse drug effects can misguide and confuse patients, preventing them from clearly seeing all the advantages and disadvantages of medical treatments that involve certain medicaments.

In attempt to quantify the percentage of under-reporting, Dr. Su Golder, Department of Health Sciences, University of York, York, UK carried out a [systematic review](#). Along with research experts from Norwich Medical School, University of East Anglia and the School of Nursing, Midwifery & Social Work, University of Manchester they indicated that only 46% of published reports contained necessary information about adverse effects. Which means that 64% of side effects are unreported. What's even more disturbing is that in 18 out of 24 study comparisons, the number of identified adverse drug effects remained bigger in unpublished documents rather than in the published ones.

Can we say that there is a serious under-reporting? Does publication bias or selective outcome reporting of adverse drug effects exist?

Definitely yes.



Yet, there are other factors that are responsible for the exclusion of important information in published medical journals. Some of them can be insufficient training of doctors to recognize ADEs or lack of knowledge about specific pharmacovigilance programmes. Many such reactions go unnoticed because of medical teams' inability to relate post effects to a drug or a treatment as well.

Running in parallel with the strong evidence that there is relatively low reporting of adverse drug effects, the need of optimized reporting procedures and practices is noticeably increasing. With much of the information on AEs remaining unpublished, the threats to the quality of drugs, the probability of treatments' inefficacies and the problem with patients' safety escalate as days go by. The question here

is, what are experts doing to stop the issue with unpublished information? Are they really taking any measures? And how soon will they solve the problem?

In relation to this subject matter, Astra Nova offers a comprehensive training which can be found [here](#). In brief, it provides with detailed information, guidance and insight into effective adverse event reporting. The course also outlines what exactly should be implemented in order to guarantee safety of human subjects and preserve quality of drugs.

You can find the online version of this article here: <https://crotraining.co.uk/under-reporting-of-adverse-drug-effects-in-clinical-research/>