Publication bias – extent of unreported outcomes in conference abstracts and journal articles when compared to the full report in the GSK trials register.

Chun Pang, Yoon Loke

School of Medicine, University of East Anglia, Norwich NR4 7TJ, United Kingdom

Objective To assess the extent of unreported outcomes (beneficial and adverse events) within ‘publicly reported’ materials as compared to the complete version of the pharmaceutical company trial report.

Design & setting We retrospectively reviewed randomised controlled trials from the GlaxoSmithKline (GSK) Clinical Trial Register along with their matched published versions of the same trials. We considered ‘published’ versions to be publicly available conference proceedings, abstracts, journal articles that were accessible electronically. The evaluated trials were studies of drugs that were approved between 2003 and 2008.

Main outcome measures Assessing the completeness of reporting for primary outcomes and secondary outcomes, as well as adverse events.

Results 54 phase III and/or IV trials covering 385 outcomes and 1626 adverse effects were identified from the GSK trials register covering Lapatinib, Abacavir, Fosamprenavir and Rosiglitazone. We were able to review publicly available electronic conference or journal ‘published’ versions for 34 out of these 73 (47%) trials. When compared with the company reports, nine of 31 (29.0%) primary outcomes went unreported and 47 of a total of 73 (64.4%) secondary outcomes were not reported in the published versions. For adverse effects, 169 of a total 198 (85.4%) ‘fatal’ events, 1071 of 1147 (93.3%) of ‘serious’ adverse events and 190 of 281 (67.6%) ‘most frequent’ adverse events were not reported in the publicly available ‘published’ versions. Overall, 1430 of 1626 (87.9%) of all adverse effects were never reported.

Conclusion For systematic reviewers, the GSK full report provides complete reporting of all main outcome and adverse effect data that is often not publicly made available elsewhere. Selective outcome reporting in published articles occurs frequently, with limited reporting of serious and fatal adverse events in conference or journal publications being of particular concern. All pharmaceutical company trial registers should provide full reporting to the same extent as the GSK register.