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Reply to Letter to the Editor

John F. Scoggins, PhD, MS* and Donald L. Patrick, PhD, MSPH

Sir,

In Scoggins and Patrick [1] we reported that 2,482 (14.0%) of 17,704 interventional clinical trials registered in ClinicalTrials.gov [2] between September 2004 and September 2007 used patient-reported outcome (PRO) instruments. Our search terms included “quality of life”, “qol”, “patient-reported outcome”, “health status”, “patient satisfaction”, and “psychometric”. We also searched for the names of 395 known PRO instruments. McEntegart [3] wonders if the percentage is actually higher than 14.0%. He cites “diary” as an obvious omission from our search terms and lists “patients assessment”, “patients global assessment”, “sleep questionnaire”, “patient questionnaires”, “subjective sleep”, “patient rated”, “patient rating”, “daily pain rating” and “patient symptom assessment” as additional terms that should have been included. To bolster his claim, the author states that a search of the ClinicalTrials.gov database on 17 May 2009 for “diary” found 892 trials. Mr. McEntegart also examines 126 clinical trials registered in ClinicalTrials.gov that utilized an interactive voice response (IVR) system to collect PRO data. From his examination he concludes that our search criteria would have only found 42.9% of the trials that used PRO instruments.

Mr. McEntegart’s comments do not accurately represent the methodology reported in our article. We did not simply search for the existence of PRO-related terms in the ClinicalTrials.gov database. To have done so would have grossly over-estimated the number of trials that use PRO instruments. For example, just because the term “quality of life” appears in a trial registry does not prove that a PRO instrument was in fact used. To have a reasonable level of specificity, we carefully read the trial registries of all trials that included at least one of our search terms and did not name a specific PRO instrument in the outcomes section. Secondly, we restricted our analysis to intervention studies. Many “trials” registered in ClinicalTrials.gov are actually retrospective observational studies. This was a restriction that Mr. McEntegart did not consider in his own search. Thirdly, we also restricted our analysis only to trials registered between September 2004, when pre-accrual registration became a requirement for publication in most journals, and September 2007, when we made a local copy of the database. Copying the database was necessary for compiling statistics on trial characteristics, such as phase, type of sponsor, etc. The 892 registered trials that contain “diary” would have included trials registered since the registry’s inception in 1999 and up to the present year. Lastly, Mr. McEntegart’s examination of 126 registered clinical trials bears little relevance to the research question we attempted to answer, i.e. what percent of registered trials use PRO instruments?

*scoggins@u.washington.edu.

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To test Mr. McEntegart's hypothesis that searching for "diary" would have significantly increased our count of the number of trials using PRO instruments, we added it to our list of search terms and repeated our study. We found 18 additional trials that would have been counted as trials that used PRO instruments had we included "diary" in our list of search terms. Since the number of trials that met our study criteria was 17,704, by including "diary" in the search terms, the percentage of PRO trials would have increased from 14.0% to 14.1%, a difference of one tenth of one percentage point. From our reading of the trial registries, we noted that often the diary in question was used to monitor the participants' adherence to a dietary regimen rather than as an outcome measurement. Diaries were often used to monitor the day to day fluctuations in signs or symptoms, such as frequency of bowel movements and body temperature. There were also many trials that were already counted as a PRO instrument trial because they included the specific name of a PRO instrument or one of the PRO-related search terms we had searched for initially.

In summation, we believe our estimate that 14.0% of registered clinical trials use a PRO instrument is accurate and reliable.

References

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3. McEntegart D. Letter to the editor re Scoggins and Patrick. 10.1016/j.cct.2009.06.001