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Title: How accurate are assessments of exacerbations through patient self-reports?

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Body: Background Patient self-report is the most common method to ascertain COPD exacerbations but its accuracy is unknown. Low accuracy of measurements leads to underestimation of treatment effects. Aims and objectives To evaluate the accuracy of different methods to ascertain COPD exacerbations in longitudinal studies and to estimate the effect of misclassification in randomised trials. Methods We used event-based definition of exacerbations that required newly prescribed systemic corticosteroids and/or antibiotics. Methods to ascertain exacerbations in 411 primary care COPD patients from ICE COLD ERIC cohort over 3 years included (1) 6-months follow-ups and (2) review of patient charts by an experienced physician. These 2 methods were compared against reference standard of adjudication committee (AC) where 3-4 experienced physicians independently adjudicated exacerbations followed by AC meeting where consensus on final classifications was reached. We calculated sensitivity and specificity and re-estimated the effects of long-acting bronchodilators vs. placebo on exacerbations by correcting for misclassification. Results 59.6% of 411 patients had at least 1 exacerbation during the 3 years according to the AC. Patient self-reports had a sensitivity and specificity of 84% and 75%, adjudication by single physicians between 88-96% and 87-99%. The pooled relative risk reduction from meta-analysis changed from 11% (95% CI 1-20%) to 35% (4-56%) when corrected for misclassification. Conclusions Conventional methods to assess exacerbations without central adjudication are likely to underestimate treatment effects substantially. Use of central or expert adjudication could reduce sample size requirements by up to 5-fold.