ERS statement: a core outcome set for clinical trials evaluating the management of COPD exacerbations

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Shareable abstract (@ERSpublications)
@EuroRespSoc Statement: A core outcome set and outcome measurement instruments for ClinicalTrials evaluating COPD exacerbations management was developed, based on evidence-informed, global, multi-stakeholder consensus https://bit.ly/3maLXiA


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Abstract
Clinical trials evaluating the management of acute exacerbations of COPD assess heterogeneous outcomes, often omitting those that are clinically relevant or more important to patients. We have developed a core outcome set, a consensus-based minimum set of important outcomes that we recommend are evaluated in all future clinical trials on exacerbations management, to improve their quality and comparability. COPD exacerbations outcomes were identified through methodological systematic reviews and qualitative interviews with 86 patients from 11 countries globally. The most critical outcomes were prioritised for inclusion in the core outcome set through a two-round Delphi survey completed by 1063 participants (256 patients, 488 health professionals and 319 clinical academics) from 88 countries in five continents. Two global, multi-stakeholder, virtual consensus meetings were conducted to 1) finalise the core outcome set and 2) prioritise a single measurement instrument to be used for evaluating each of the prioritised outcomes. Consensus was informed by rigorous methodological systematic reviews. The views of patients with COPD were accounted for at all stages of the project. Survival, treatment success, breathlessness, quality of life, activities of daily living, the need for a higher level of care, arterial blood gases, disease progression, future exacerbations and hospital admissions, treatment safety and adherence were all included in the core outcome set. Focused methodological research was recommended to further validate and optimise some of the selected measurement instruments. The panel did not consider the prioritised set of outcomes and associated measurement instruments to be burdensome for patients and health professionals to use.