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Title: The minimal clinically important difference (MCID) for the six minute walk (6MW) test in COPD in relation to death

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Body: Introduction: The 6MW is used to assess interventions in COPD but existing estimates of the MCID for have been derived from narrow cohorts where a non-blinded intervention, for example pulmonary rehabilitation, have been applied. Objective: To define the MCID for 6MW distance in an unselected population. Methods: Data from the ECLIPSE cohort were used. Briefly 2112 patients were prospectively followed for 3 years in a multicentre study. We defined an index event as death or first hospitalisation and

calculated the change in 6MW (Δ 6MW) in the last 12 month period before the event occurred. If a patient did not have an event the last 12 month change was used. We also related Δ 6MW to commonly used outcome measures in COPD; FEV₁ and St Georges Respiratory Questionnaire (SGRQ-C). Results: Of the subjects with Δ 6MW, 94 patients died and 323 were hospitalised. 6MW fell by mean (SD) 29.7 (82.9)m more in those who died than survivors ($p < 0.001$). No significant difference in Δ 6MW was observed in those who had a first hospitalisation than those who did not. Cox proportional hazard modelling showed that a Δ 6MW of more than -30 m conferred a hazard ratio of 1.93 (95% CI: 1.29, 2.90; $p = 0.001$) for death. Weak relationships only were observed between Δ 6MW and Δ FEV₁ or Δ SGRQ. Conclusions: A fall in 6MW of 30m or more is associated with increased risk of death in patients with COPD and therefore represents a clinically significant MCID for this test. The modest relationships between Δ 6MW and Δ FEV₁ or Δ SGRQ suggest that anchor based methods for determining MCID are context dependent. Funded by GSK (SCO104960; NCT00292552).