

European Respiratory Society Annual Congress 2013

Abstract Number: 614

Publication Number: 2010

Abstract Group: 1.6. General Practice and Primary Care

Keyword 1: COPD - management **Keyword 2:** COPD - exacerbations **Keyword 3:** Primary care

Title: Real-life COPD patients compared to large trial populations: An UNLOCK external validity study

Mrs. Annemarije 6058 Kruis a.l.kruis@lumc.nl MD ¹, Mr. Bjorn 6059 Ställberg b.stallberg@saalem.mail.telia.com MD ², Dr. Rupert 6060 Jones rupert.jones@pms.ac.uk MD ³, Dr. Ioanna 6061 Tsiligianni pdkapa@yahoo.gr MD ⁴, Dr. Jan Willem 6062 Kocks <J.W.H.Kocks@med.umcg.nl MD ⁵, Prof. Dr Thys 6063 van der Molen T.van.der.Molen@med.umcg.nl MD ⁵ and Dr. Niels 6064 Chavannes n.h.chavannes@lumc.nl MD ¹. ¹ Department of Public Health and Primary Care, Leiden University Medical Center, Leiden, Netherlands ; ² Department of Public Health and Caring Sciences, Family Medicine and Preventive Medicine, Uppsala University, Uppsala, Sweden ; ³ Peninsula Medical School, University of Plymouth, Plymouth, United Kingdom ; ⁴ Department of Thoracic Medicine, University of Crete, Heraklion, Greece and ⁵ Department of General Practice, University Medical Center Groningen, Groningen, Netherlands .

Body: Objective To investigate the external validity of six large randomized controlled medication trials (ISOLDE, TRISTAN, TORCH, UPLIFT, ECLIPSE, POET-COPD) compared to the COPD population seen in the community, and to examine the proportion of patients in the community that would be selected based on inclusion criteria of these trials. Results We combined 7 primary care databases including 3508 COPD patients from the Netherlands, Sweden, the United Kingdom and Greece in the UNLOCK study. We compared baseline characteristics of the trials to UNLOCK patients. Trials included more male subjects (73%) with more pack years (45), whereas in the community 46% were females with 39 pack years. There were differences in GOLD stages: community based data showed a majority of GOLD I (24%) and GOLD II (54%) patients, in trials GOLD I was absent and 35-48% were GOLD II, 42-49% GOLD III and 9-15% were GOLD IV patients. Mean exacerbation rates were higher in trials (0.8 vs. 1.19), with an overrepresentation of patients with ≥ 2 exacerbations (31% vs. 19% community). Mean exacerbation rate distributed per GOLD stage demonstrated exacerbation rates increased per GOLD stage, however mean rates in the community were lower in all GOLD stages compared to the trials, except in the UPLIFT trial. The proportion of COPD patients from the community that could be included in the trials ranged from 17% (TRISTAN trial) to 48% (ECLIPSE, UPLIFT trial). Conclusion Large medication RCTs included highly selected COPD populations; these are predominantly men with worse lung function, more pack years and more exacerbations per year. It still remains highly uncertain if results of these trials can be applied to all COPD patients.