spent on over-the-counter cough medicines annually, despite limited evidence to support their efficacy. The optimal cough assessment outcome parameter for clinical evaluation of anti-tussive drugs is not known. We investigated the natural course of acute cough with objective and subjective cough assessment tools.

**Methods**

S2 healthy subjects with acute cough due to upper respiratory tract infection (median (IQR) age 30 (32–55) years, 63% female, mean (SEM) duration of cough 4.2 (0.4) days) were recruited for evaluation. Assessments including anti-tussives were excluded. Assessments of cough severity included objective 24-h ambulatory cough frequency monitoring with the Leicester Cough Monitor, health related quality of life (HRQOL) with the Leicester Cough Questionnaire-Acute (LCQ) and cough severity visual analogue scale (VAS). Assessments were performed at baseline (day 1) and then 4 and 8 days later. Global rating of change questionnaires were completed by patients at each follow-up to assess change in cough severity and determine minimal important difference.

**Results**

At baseline, the median (IQR) LCQ score was 14.7 (10.9–18.3) and mean (SEM) cough VAS was 48 (4) mm, consistent with a severe cough associated with significant impairment in HRQOL. Geometric mean (logSD) 24-h cough frequency (CF24) at baseline was 15.0 (0.4) coughs/hr, and at days 5 and 9 were 8.7 (0.5) and 5.4 (0.7) coughs/hr respectively. At day 5, 5 subjects reported no change, 9 mild, 14 moderate and 6 large change in their cough severity. At day 9, 6 subjects reported mild, 5 moderate and 20 large change in cough severity. The minimal important difference on day 5 for the LCQ was 2.0, VAS 17 mm and CF24 54% change from baseline.

**Conclusions**

Acute cough is associated with a significant cough frequency and impairment in HRQOL. We suggest clinical trials of anti-tussive drugs should incorporate objective and subjective cough assessment outcome measures. Anti-tussive drugs need to demonstrate a considerable reduction in cough frequency (>54% over a 4-day interval) to establish clinically important efficacy.