Development of a COPD Exacerbation Recognition Tool (CERT) for use by Chinese patients: item reduction and final content

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Background

- Patients under report exacerbations of COPD [1, 2]
- Unreported exacerbations have similar outcomes to reported one[1, 3–5].
- A key factor for under-reporting may be patients' lack of understanding of the significance of worsening symptoms.
- The objective was to develop a COPD Exacerbation Tool (CERT) to provide patients with guidance about seeking medical attention when they worsened.
- The qualitative identification of 29 symptoms experienced by patients with an exacerbation has been presented at ATS 2019[6].
- This poster reports item reduction and selection of CERT items.
- To ensure that the CERT was concise and easy for patients to use a target of 5 CERT items was set *a priori*.

Methods

- The previously identified 29 candidate items were completed by 150 patients in three centres in China (north, south west and east mainland China), 50 per centre.
- Each item had two types of response formats:
  - Severity during the exacerbation (Severity):
    "Not experienced", "As usual", "Mild", "Moderate", "Severe"
  - Change from Usual State (Change):
    "Not experienced", "As usual", "Mild", "Moderate", "Severe"
- The association between item responses and demographic factors was tested.
- Exploratory factor analysis (EFA) was used to identify domains.
- A panel of statisticians, patient reported outcome specialists and clinicians, took into account all the data to ensure an adequate balance of items based on frequency response and factor loading in the EFA.

Inclusion and exclusion criteria

- Inclusion criteria
  - male or female; age ≥40 years, spirometrically confirmed COPD; treated COPD exacerbation within 3 months prior to the study visit; informed consent.
- Exclusion criteria
  - current diagnosis of asthma or clinically relevant bronchiectasis, concurrent significant, uncontrolled, other active medical condition

Results

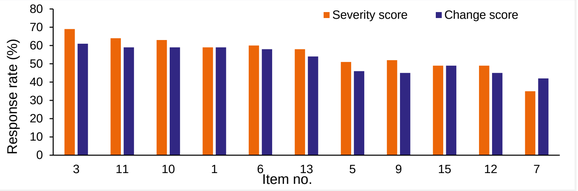
Table 1 Demographics

Age	69 years
Smoking status (%)	
Current	35%
Ex-smokers	42%
Never smokers	23%
FEV_1 (% pred)	63%
CAT score	15
Exacerbation frequency in previous year (median)	
Moderate	2
Hospitalised	2
Education level (%)	
Primary school	27%
Middle school	48%
College or above	17%
Illiterate	9%

Table 2 Response rates

	Mean	Range
Severity score		
Moderate and severe combined	43%	2-69%
Severe	9%	0-17%
Change score		
Moderate and severe combined	38%	<1-61%
Severe	8%	0-21%

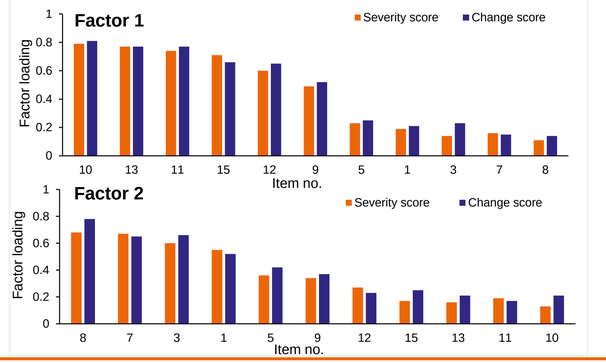
Figure 1. Response rates for top 11 ranked items



Results summary

- Items with highest response rates (Figure 1), average shared variance with
  - gender 1.1%
  - education 4.5%
  - age 1.1%
  - height 0.5%
- Percentage of patients with low item symptom scores
  - Lower education groups 44%
  - Higher education groups 46%
- Top 11 items were submitted to EFA (Figure 2); scree plot suggested a 2-factor solution for both response options.
  - Factor 1 Eigenvalues:
    - Severity score 8.31 (79.1% of variance)
    - Change score 10.19 (80.1% of variance)
  - Factor 2 Eigenvalues
    - Severity score 2.19 (20.9% of variance)
    - Change score 2.52 (19.9% of variance)

Figure 2. Factor Loadings for Severity score and Change score



Summary and Conclusions

- **Two factors were identified:**
  - **Factor 1 breathlessness and activity limitation**
  - **Factor 2 cough and sputum**
- **Five items were selected for the CERT based on frequency and factor analysis:**
  - **Worsening cough**
  - **Increased volume of sputum**
  - **Shortness of breath**
  - **Laboured breathing**
  - **Limitation of activity**

Table 3 Mean response rate and mean factor loading (Severity & Change scores combined)

Item no.	Description	Factor loading	Response rate (%)
Factor 1			
Item 10	Labored breathing	0.80	59%
Item 13	Limitation of activity	0.77	56%
Item 11	Shortness of breath	0.76	61%
Item 15	Exhaustion & fatigue	0.69	49%
Item 12	Chest distress	0.63	47%
Item 9	Abnormal sound during breathing (wheezing)	0.51	49%
Factor 2			
Item 8	Increased volume of sputum.	0.73	62%
Item 7	Color of sputum changes	0.66	39%
Item 3	Worsening of cough	0.63	65%
Item 1	Appearance of purulent/thick sputum	0.54	57%

References

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Disclosures

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- On behalf of all authors, an audio recording of this poster was prepared by Paul Jones, who did not receive any payment for this recording. The presenting author, Paul Jones, declares that he is a GSK employee and owns GSK stocks and shares
- YY is an employee of GlaxoSmithKline. At the time of the study, GW was an employee of GlaxoSmithKline. QM was a study investigator, consultant, a member of the advisory board and an invited speaker. YY and GW received reimbursement of travel expenses.
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