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PATIENT REPORTED OUTCOME MEASURES TO ASSESS THE EFFECTIVENESS OF INHALED MEDICATIONS IN ASTHMA

Guruparan Y[1], Selvaratnam G[2], Nalika Gunawardena[3], Thiyahiny S.N[4], Sri Ranganathan S[5]

[1]*Lecturer, Department of Pharmacology, Faculty of Medicine, University of Jaffna*

[2]*Senior Lecturer, Department of Medicine, Faculty of Medicine, University of Jaffna*

[3]*National Professional Officer, World Health Organization, Country office, Sri Lanka*

[4]*Senior Lecturer, Department of Pharmacology, Faculty of Medicine, University of Jaffna*

[5]*Professor, Department of Pharmacology, Faculty of Medicine, University of Colombo*

Objective: To develop patient reported outcome measures (PROMs) to assess the effectiveness of inhaled medications in asthma.

Methods: We developed the PROMs using the guidelines published by the Food and Drug Administration. The key steps included item generation, item reduction and psychometric evaluation. Items were generated through six focus group discussions (FGDs) with each having 6-10 adult patients with asthma attending Teaching Hospital-Jaffna. Items were reduced by two rounds of online Delphi study involving 10 experts and exploratory factor analysis (EFA) using 200 patients with asthma in another hospital. The selected items were converted to 5-point Likert scale statements. Reliability and validity of the PROMs were assessed.

Results: From thematic analysis of the FGDs 16 items (PROMs) were generated and reviewed independently by clinical pharmacologist and the principal investigator. Out of 16 items10 were selected for Delphi study. At the end of Delphi study 9 items which scored four or above on Likert scale with 80% of consensus among experts were selected for EFA. After EFA 8 items were retained, which are: cough becomes less, less wheezing, can breathe without difficulties, heaviness of my chest becomes less, frequency of nebulization becomes less, hospitalization is reduced, can sleep well and can do my routine household activities. For these 8 items Cronbach's α coefficient was above 0.7. Face and content validity were assessed by experts.

Conclusion: The developed PROMs can be used to assess the effectiveness of inhaled medications in adult patients with asthma in the local context.