

Development and validation of the Respiratory Adherence Care Enhancement (RACE) questionnaire, facilitating personalised pharmaceutical care of asthma patients with inhaled corticosteroids (ICS)

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Background Inhaled corticosteroids (ICS) are considered the cornerstone of maintenance therapy for asthma. In clinical practice adherence to ICS remains suboptimal in asthma patients. Driving factors for non-adherence are complex and consist of a range of barriers with a considerable inter-individual variability. The Theoretical Domains Framework (TDF) offers a set of behavioural determinants explaining these barriers. Identification of individual patient barriers to ICS use may enable personalised pharmaceutical care to improve adherence and treatment outcomes.

Purpose This study aims to develop and validate the RACE questionnaire to identify personalized barriers for ICS use in primary care asthma patients.

Method The development of the RACE-questionnaire was based upon a literature review and Delphi Rounds with expert panels. The prototype consisted of the following 6 TDF-domains: 'Knowledge', 'Beliefs about consequences', 'Effort', 'Skills', 'Behavioural regulation' and 'Memory, attention and decision process'. Within these domains a total of 10 constructs were defined corresponding to potential barriers for ICS use with a total of 22 questions divided over the constructs. Answers to the questionnaire were collected from primary care asthma patients on a 5-point Likert scale. Internal consistency was conducted for the scores within each construct. Subsequently, semi-structured interviews were conducted as a golden standard for the identification of barriers. The interviews were transcribed and coded by two independent researchers with a predefined framework. Cut-off values and criterion validity were assessed by comparison of the barriers mentioned in the questionnaire with the interviews.

Findings Scores from 64 patients were available from the RACE-questionnaire. Cronbach's alpha for the internal consistency of the questions within the 10 constructs ranged from 0.6 to 0.9. Interviews from 61 patients were available for the criterion validity. Optimal cut-off values were determined at a sensitivity between 41% and 83% and a specificity between 67% and 92% for all 10 constructs. All constructs showed significant Areas Under the Receiver Operating Curves with values between 0.69 and 0.86 (p -value <0.05), with the exception of 'Knowledge of ICS medication' within the TDF-domain 'Knowledge' with a value of 0.53.

Conclusion The RACE-questionnaire yields adequate metric properties to identify individual barriers for optimal ICS use in primary care asthma patients. This tool is ready to be applied in consultations to facilitate personalised pharmaceutical care in these patients. The effectiveness of this personalized support to improve patient outcomes in clinical practice needs further evaluation.