315. DEVELOPMENT OF AN ANCA-ASSOCIATED VASCULITIS PATIENT-REPORTED OUTCOME MEASURE: IDENTIFICATION OF SALIENT THEMES AND CANDIDATE QUESTIONNAIRE ITEM DEVELOPMENT

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Background: Patients with ANCA-associated vasculitides (AAVs), granulomatosis with polyangiitis, eosinophilic granulomatosis with polyangiitis (Churg–Strauss) and microscopic polyangiitis often suffer from persistent disease activity, disease-associated damage, or treatment side effects, all of which may impact quality of life. There is currently no disease-specific patient-reported outcome (PRO) for AAV. The development of a new PRO involves questionnaire item development; item reduction and scale generation; and testing scale properties such as reliability, validity and responsiveness. It is essential that a PRO is developed in compliance with U.S. Food and Drug Administration recommendations in order to legitimize its use in clinical trials and in supporting labelling claims for medications. Following these principles, a multi-national collaboration of researchers and patient-partners has been conducting the first stage of questionnaire
item development. A collaborative approach involving patients from the UK, USA and Canada was feasible and desirable due to the relative rarity of the disease and the ability to create a tool with content validity (and cultural/linguistic equivalence) appropriate for use in all three countries.

**Methods:** Exploratory semi-structured patient interviews were performed in Oxford, UK, Philadelphia, USA, and Ottawa, Canada. The aim was to identify salient dimensions of quality of life and perceived problems of health status related to having AAV. The overall sample size was determined by the point at which no new themes emerged from interviews (saturation), and was also guided by a purposive sampling framework to ensure that the broadest range of experiences possible was captured. Thus, patients of both sexes, various ages, with all three forms of AAV, different disease durations, stages and extent of organ involvement were included. Researchers (within and across research groups) independently scrutinized interview transcripts for relevant themes. Themes identified from transcripts were then re-cast as candidate questionnaire items. Regular teleconferences maintained equivalence of methods and exchange of relevant themes.

**Results:** Fifty semi-structured interviews of patients with AAV were performed in Oxford (19), Ottawa (14) and Philadelphia (17) using standardized prompts and cues. After transcription and scrutiny, 60 distinct themes related to having AAV were identified, including symptoms (related to condition or treatment) and the ways in which these symptoms influenced patients’ ability to work, activities of daily living, engagement in social activities, and state of mind (see Table 1 for the evolving conceptual framework).

**Conclusion:** A list of themes and candidate items has been produced, drawn directly from patient experience, to inform the development of a PRO for AAV. Next steps include piloting the candidate questionnaire items through cognitive interviews, surveying ~500 patients to produce an instrument with appropriate scale structure, measurement properties and scoring algorithms. This will be followed by a multi-centred prospective validation study.

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