Both AS and nr-axSpA patients confirmed the three PROMIS Short Forms to be adequate assess key impacts associated with axSpA, making them suitable for use in clinical trials of patients with axSpA.

**Background:** Axial spondylarthritis (axSpA) is characterised by inflammation of the sacroiliac joints and spine. Sleep disturbance, pain and fatigue are reported in the literature to be key symptoms and impacts of axSpA. Three customised Patient-Reported Outcomes Measurement Information System (PROMIS) Short Forms (Sleep Disturbance, Pain Interference and Fatigue) were developed in 2012 by the National Institutes of Health-funded PROMIS team. The PROMIS team created PROMIS Short Forms to support their use as endpoints in axSpA clinical trials.

**Objectives:** To conduct in-depth qualitative interviews to further understand the patient experience of axSpA and evaluate the content validity of the three PROMIS Short Forms to support their use as endpoints in axSpA clinical trials.

**Methods:** A non-interventional, cross-sectional qualitative (concept elicitation [CE] and cognitive debriefing [CD]) study was conducted to 28 adult patients with diagnosed axSpA. The interviews were semi-structured and ended questions to elicit information about symptoms and impact experienced by patients. The CD section involved a ‘think-aloud’ exercise in which patients read out each instruction, item, and response option for the three PROMIS Short Forms and shared their feedback. Patients were also asked detailed questions about the relevance of the items, response options, and recall period. Verbatim interview transcripts were subject to thematic and content analysis.

**Results:** Patients were from the United States (n=20) and Germany (n=8), mean age was 52.8 years, and 57% (n=16) were male; mean time since diagnosis of axSpA was 9.5 years (range 0.3–31.3 years). The CE section identified 12 distinct signs and symptoms that characterised patients’ experience of axSpA: pain, sleep problems, fatigue/tiredness, stiffness, swelling, vision/eye issues, restricted body movements, headache/migraine, spasms, change in posture/stature, balance/problems, fatigue/tiredness, stiffness, swelling, vision/eye issues, restricted body movements, headache/migraine, spasms, change in posture/stature, balance/problems. Pain, sleep problems and fatigue/tiredness were all reported to be experienced by ≥90% of patients, occurring simultaneously and exacerbating one another. 78% (n=21/27) of patients reported pain to be the most bothersome symptom, and 88% (n=23/26) described it as the symptom they would most like treatment to improve. Patients reported axSpA to impact their lives across six health-related quality of life (HRQoL) domains: physical functioning (100%), emotional wellbeing (89%), work/volunteer functioning (79%), social functioning (75%), activities of daily living (61%) and cognitive functioning (54%). Impacts were most frequently described as being associated with pain, stiffness and fatigue. The experiences of symptoms and impacts were consistent between the AS and nr-axSpA patients. CD showed all three PROMIS instruments are conceptually comprehensive and well understood by patients with axSpA. No patients reported misunderstanding of instructions and/or items of the sleep disturbance instrument, and only one and four items had a small number of instances of misunderstanding for the fatigue and pain interference instruments, respectively. Across each instrument, all items were relevant to at least half of patients, and almost all patients reported the instruments to be appropriate for measuring their experience of sleep problems, pain and fatigue due to axSpA. Both AS and nr-axSpA patients confirmed the three PROMIS Short Forms to be relevant and appropriate for assessing their disease experience.

**Conclusion:** Pain, sleep problems and fatigue are pivotal symptoms of axSpA and associated with HRQoL impacts. Interpretable and content valid PROMIS customised Short Forms have been confirmed, with each deemed to adequately assess key impacts associated with axSpA, making them suitable for use in clinical trials of patients with axSpA.

**Funding:** GSK [209770]

**Acknowledgements:** Medical writing support was provided by Tony Reardon, of Adelphi Values, who received fees from GlaxoSmithKline for the conduct of this study, Jessica Middlehurst Grant/research support from: employee of Adelphi Values, who received fees from GlaxoSmithKline for the conduct of this study, Chloe Howse Grant/research support from: employee of Adelphi Values, who received fees from GlaxoSmithKline for the conduct of this study.

**Disclosure of interests:** Amy Findley Grant/research support from: employee of Adelphi Values, who received fees from GlaxoSmithKline for the conduct of this study, William Neill Grant/research support from: employee of Adelphi Values, who received fees from GlaxoSmithKline for the conduct of this study, Sophi Tatlock Grant/research support from: employee of Adelphi Values, who received fees from GlaxoSmithKline for the conduct of this study, Wen-Hung Chen Shareholder of: GlaxoSmithKline, Employee of: GlaxoSmithKline, Margaret Bracher Shareholder of: GlaxoSmithKline, Employee of: GlaxoSmithKline, Dharm Patel Shareholder of: GlaxoSmithKline, Employee of: GlaxoSmithKline