



3.1 Questionnaire Design

This cross-sectional market research survey was adapted from the Spanish Atlas of Axial Spondyloarthritis 2017, a pilot survey conducted from January to March 2016 (Garrido-Cumbrera et al. 2019a).

The first draft of the questionnaire was completed by 25 patients with different sociodemographic profiles to assess the feasibility and adequacy of the questions. The questionnaire was subsequently translated into relevant local languages: English, Dutch, French, German, Italian, Norwegian, Russian, Swedish, and Slovenian. Participating countries could modify questions for local relevance, with guidance only to make essential changes in order to maintain consistency on a pan-European level (Garrido-Cumbrera et al. 2019b).

The final patient questionnaire contained a total of 108 items related to sociodemographic and anthropometric characteristics, patient organization membership, diagnostic delay (date of first symptoms and diagnosis with axSpA), healthcare resource use, comorbidities, drug treatments, employment and work productivity, disability benefits, functional limitations, complementary treatments, and patient experience of living with the disease (Garrido-Cumbrera et al. 2019b).

The study utilized relevant information from a literature search to validate and support the responses from both questionnaires. Documents developed by the Assessment of SpondyloArthritis international Society (ASAS) were also consulted to supplement literature searches.

Supplementary Information The online version contains supplementary material available at https://doi.org/10.1007/978-3-030-97606-4_3.

3.2 Implementation of the Survey

Patients meeting the following inclusion criteria were recruited between July 2017 and March 2018:

- Aged ≥ 18 years.
- Residents in the specified country.
- A diagnosis of axSpA, AS, or nr-axSpA (self-reported).
- Visit to HCP for axSpA in the 12 months prior to participation.

Participants from Austria, Belgium, France, Germany, Italy, Netherlands, Norway, Russia, Slovenia, Sweden, Switzerland, and the UK were recruited by GfK through their existing database of respondents. In Austria, France, Norway, Slovenia, Sweden, the Netherlands, Italy, and Russia, patient organizations also supported recruitment by distributing the survey to members. The Spanish database from the Atlas of Axial Spondyloarthritis 2017 was retrospectively added.

The survey conducted in Spain was administered via SurveyMonkey, an online platform for survey data collection, and conducted by HTR. Coordination of the patient survey and data collection in European countries other than Spain was led by Ipsos (formerly GfK).

3.3 Supplementary Instruments

A range of supplementary indices were collected in the questionnaire.

1. **Spinal Stiffness Index:** an index developed by the University of Seville specifically for the IMAS European survey (Garrido-Cumbrera et al. 2019a) to assess the degree of spinal stiffness experienced by patients in the spinal column, distinguishing between the cervical, dorsal, and lumbar areas.
2. **Functional Limitation Index:** a measure designed by the University of Seville specifically for the IMAS European survey (Garrido-Cumbrera et al. 2019a) to assess the degree of functional limitation in 18 activities of daily life: dressing; bathing; grooming; tying shoe laces; moving about the house; climbing stairs; getting into/out of bed; using the bathroom; shopping; preparing meals; eating; household cleaning; walking down the street; using public transportation; going to the doctor; driving; doing physical exercise; having sex.
3. **Bath Ankylosing Spondylitis Disease Activity Index (BASDAI)** (Garrett et al. 1994): a self-administered questionnaire that evaluates disease activity in patients with axSpA. It includes six questions relating to the following symptoms: fatigue; pain in the spinal column; inflammation/pain in joints other than the neck, back, and hips; areas of localized tenderness (also called enthesitis, or inflammation of tendons and ligaments); and the level and duration of stiffness in the morning.

4. **12-item General Health Questionnaire (GHQ-12)** (Goldberg 1972): is a screening instrument for assessing risk of psychological distress that has been widely used in various settings across different cultures.

3.4 Statistical Analysis

Data from completed questionnaires were harvested to compile the study database, which underwent data cleaning, homogenization, and normalization of the variables prior to analysis.

Different statistical tests were applied depending on the nature of the variable (qualitative or quantitative) and the sample distribution (parametric or non-parametric).

3.4.1 Quantitative Analysis

The Kolmogorov–Smirnov test was used to test the normality of all quantitative variables. For those variables whose distribution did not fulfil certain assumptions such as normality and homoscedasticity, non-parametric tests were applied:

- Mann–Whitney U test for independent samples (2 groups).
- Kruskal–Wallis H test for independent samples (>2 groups).
- Pearson χ^2 test to verify whether there is a relationship between two categorical variables.
- Spearman’s rank correlation coefficient was used to measure the association or relationship of monotony between pairs of quantitative variables.
- The Pearson correlation coefficient was used for cardinal quantitative variables to measure the linear relationship between two variables.

3.4.2 Qualitative Analysis

The questionnaire included the following open questions:

1. Please describe your fears in relation to your spondylitis/spondyloarthritis.
2. Please describe your hopes in relation to your spondylitis/spondyloarthritis.
3. Please describe your personal treatment goals for spondylitis/spondyloarthritis.

In France, the third question was excluded and the first two questions were multiple choice.

The qualitative answers were homogenized (taking into account the options presented in the case of France), standardized, and grouped into several areas, including the frequency of each type of response. This allowed qualitative questions

to be converted into quantitative, count percentages of answers, and thus assess patients' priorities in relation to their hopes and fears in general, as well as their goals with respect to their treatments.

3.5 Steering Committee

A multi-stakeholder steering committee of axSpA experts (rheumatologists, psychologists, researchers, and patient representatives) from several European countries was selected to:

- Guide strategy and data analysis.
- Provide expert responses to any questions emerging during the project.
- Interpret the results (both quantitative and qualitative).
- Provide scientific documents to support report preparation (including scientific literature and official reports).
- Support dissemination of the results.

The members of the steering committee for the IMAS European project are listed in the Contributors section.

Steering committees at the country level were organized in 8 of the 12 participating countries (all except Austria, Belgium, Germany, and the UK) to support local interpretation and dissemination of results.

3.6 Literature Review

The study utilized relevant information identified from a literature search to validate and support the responses from both questionnaires.

Searches were conducted using PubMed and Scopus with the keywords 'axial spondyloarthritis' and 'ankylosing spondylitis' together with other terms depending on the topic, such as:

- Employment: 'labour', 'employment', 'disability', 'absenteeism', or 'presenteeism'.
- Treatment: 'pharmacological treatments', 'drugs', or 'physical activity'.
- Health status: 'disease activity', 'stiffness', or 'functional limitation'.
- Well-being: 'mental health', 'psychological', 'psychiatric', 'anxiety', or 'depression'.
- Daily life: 'unhealthy habits', 'smoking', or 'alcohol'.
- Patient perspective: 'support group' or 'patient perspective'.

The search was limited to articles published between 2000 and 2018, giving priority to studies conducted in Europe compared with the rest of the world.

Documents developed by the Assessment in SpondyloArthritis international Society (ASAS) were also consulted to supplement literature searches.

3.7 Report

The data gathered using the questionnaire were used to prepare two types of report: a) an axSpA Country Profile for each country and b) an axSpA Pan-European report. The reports were prepared by the University of Seville. All members of the steering committee critically reviewed and approved the reports prior to publication.

Funding The IMAS European project was funded by Novartis Pharma AG, Basel, Switzerland (Supplemental Information for Chap. 3).

References

- Garrett S, Jenkinson T, Kennedy LG, et al. A new approach to defining disease status in ankylosing spondylitis: the bath ankylosing spondylitis disease activity index. *J Rheumatol*. 1994;21:2286–91.
- Garrido-Cumbrera M, Navarro-Compan V, Zarco P, et al. Atlas of axial spondyloarthritis in Spain 2017: study design and population. *Reumatol Clin*. 2019a;15:127–32.
- Garrido-Cumbrera M, Poddubnyy D, Gossec L, et al. The European Map of Axial Spondyloarthritis: capturing the patient perspective—an analysis of 2846 patients across 13 countries. *Curr Rheumatol Rep*. 2019b;21(5):19.
- Goldberg DP. The detection of psychiatric illness by questionnaire: a technique for the identification and assessment of non-psychotic psychiatric illness. Oxford, England: Oxford University Press; 1972.

Open Access This chapter is licensed under the terms of the Creative Commons Attribution 4.0 International License (<http://creativecommons.org/licenses/by/4.0/>), which permits use, sharing, adaptation, distribution and reproduction in any medium or format, as long as you give appropriate credit to the original author(s) and the source, provide a link to the Creative Commons license and indicate if changes were made.

The images or other third party material in this chapter are included in the chapter's Creative Commons license, unless indicated otherwise in a credit line to the material. If material is not included in the chapter's Creative Commons license and your intended use is not permitted by statutory regulation or exceeds the permitted use, you will need to obtain permission directly from the copyright holder.

