

Assessment of the patient's perspective in the European Register for Multiple Sclerosis (EUREMS): Study protocol of the PRO study

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Background: The EUREMS (European Register for Multiple Sclerosis) project was designed as a platform to analyse and compare data of persons with MS (PwMS) within the EU member states. Herewith we report design and first results of a test study on patient-reported outcomes (PRO) that was developed to address one of the four EUREMS missions, namely the “assessment of PwMS’ quality of life (QoL), burden of symptoms and socio-economic aspects from the patient’s perspective”. The main interest here is the identification of differences in QoL and employment between participating countries.

Methods: After identifying the existing registers in Europe, questionnaires and semi-structured interviews were conducted in order to assess the register’s heterogeneity and their ability to participate. Based on these results, four registers (Germany, Poland, Sweden and UK) were identified to participate in the first stage of this study. A set of variables was identified in close cooperation between the registers and the Department of Medical Informatics at the University Medical Center in Göttingen, Germany, which represents the required information on demographics, basic disease characteristics, PRO data (i. e. EQ5d, MSIS-29), and data on employment.

Results: A EUREMS database was set up, and import frameworks were developed providing information on specifications and definitions for data items, guidance on data anonymization and data transfer, and supported export formats. Standard routines were developed to harmonize the heterogeneous datasets from different registers by mapping the national register data to the EUREMS PRO dataset and according metadata. Data transfer is being performed by a file transfer service. To refine procedures for data harmonization and data analyses, the registers were asked to transmit test data. The statistical models for comparing the register data between European countries were defined according to the hypotheses that have been formulated by the EUREMS group. Data are now analysed, first results will be presented during the meeting.

Conclusions: The test phase of this EUREMS study will enable the consortium to (1) improve processes and tools for the integration and comprehensive analyses of PRO data from

different sources across Europe, (2) show whether it is feasible to collect PRO data in a considerable number of PwMS on a European level, and (3) compare QoL and employment of PwMS in selected European countries.