Assessment of the patients' perspective in the European Register for Multiple Sclerosis (EUReMS): Study protocol and first results of the PRO study

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EUReMS project and studies

With the general aim of establishing a European-wide platform for systematic analysis and comparison of longitudinally collected MS data in Europe, the European Register for Multiple Sclerosis (EUReMS) project was set up in 2010 by an international and interdisciplinary consortium. It is co-funded by the European public health program and involves both, scientists and patient organisations.

Based on the assumption that a comprehensive approach to and harmonization of MS data collection at a European level are needed, a consensus statement on EUReMS' vision, mission and strategies was approved[1]. Based on the herein defined areas of action, four test studies were defined:

DMD1 Study: Comparison of access to and effectiveness of DMD treatment for people with MS (PwMS) across Europe (coordinated by Prof. J. Hillert)

EPI1-d Study: Estimating prevalence and incidence of MS in Europe from EUReMS data collection (coordinated by Prof. M. Pugliatti)

EPI1-s Study: Comparison of the effect of the month of birth across Europe (coordinated by D. Ellenberger and Prof. M. Pugliatti)

PRO1 Study: Assessment of people with MS' quality of life (QoL), the burden of disease and influence of employment from the patients' perspective across European countries (coordinated by Prof. P. Flachenecker)

EUReMS study	DMD1	EPI1-d	EPI1-s	PRO1
Number of patients	**15,788**	**13,004**	**61,848**	**4,507**
Countries of participating registers				
Croatia			■	
Czech Republic			■	
Finland			■	
Germany	■		■	■
Italy	■	■	■	
Norway		■	■	
Poland			■	■
Serbia		■	■	
Spain		■	■	
Sweden	■	■	■	■
QR-Code				

PRO Study

We report design and first results of the test study on patient-reported outcomes (PRO) that was developed to address one of the four EUReMS missions, namely mission #4, "assessment of PwMS' QoL, burden of symptoms and socio-economic aspects from the patients' perspective". The main interest here is the identification of differences in QoL (quality of life) and employment between participating countries.

Methods

Existing registers in Europe were identified and analyzed in order to assess the register's heterogeneity and their ability to participate. Investigations were carried out using questionnaires and semi-structured interviews. Based on these results, three registers were identified to participate in the first stage of this study:

- MS-Register der DMSG, Bundesverband e.V. (Germany)
- REJSM – Polish MS register (Poland)
- SMSreg – Svenska Multipel Skleros registret (Sweden)

A set of variables was identified which represents the required information on demographics, basic disease characteristics, PRO data (i.e. EQ5d, MSIS-29), and data on employment.

A EUReMS database was set up, and import frameworks were developed providing information on specifications and definitions for data items, a guidance on data anonymization, instructions for 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 study dataset and according metadata.

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. Differences in the EQ5d index were investigated in ANCOVA regression models, while the MSIS-29 total score and its physical and psychological subscales were investigated by a non-parametric alternative of the ANCOVA. The working status was evaluated by multivariable logistic regression models accordingly.

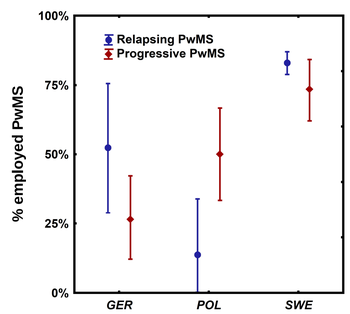
Results

	Country		
	GER	**POL**	**SWE**
Number of PwMS	61	240	4,206
% women	67 %	66 %	72 %
% relapsing-remitting	38 %	40 %	82 %
Age of onset [years]	32 (9)	35 (9)	31 (10)
Disease duration	17.7 (11.0)	13.5 (8.3)	10.3 (7.6)
% working	36 %	35 %	82 %
MSIS-29 (total)	44.0 (19.8)	36.4 (24.0)	28.0 (22.3)
MSIS-29 (physical)	46.1 (20.3)	34.7 (25.8)	26.4 (23.7)
MSIS-29 (psychological)	39.4 (21.8)	40.2 (22.0)	31.6 (24.5)
EQ5d	-	0.56 (0.28)	0.71 (0.22)
EDSS	5.3 (2.2)	3.8 (2.4)	2.5 (1.9)

Results are given as mean (standard deviation) and percentages, respectively.
GER = Germany, POL = Poland, SWE = Sweden, PwMS = persons with MS.
The total and sub-scores of the MSIS-29 (Multiple Sclerosis Impact Scale) were normalized to 0–100 (%), with lower scores indicating less impact of the disease, whereas lower scores of the EuroQoL-5d Single Summary Index [Europe] (EQ5d) indicate lower levels of QoL.

Multivariable analyses showed significant differences ($p<0.01$) between males and females in all QoL (sub-)scores indicating that females are in general more severely affected.

The influence of the disease course (relapsing vs. progressing) strongly varied between the three countries in all scores ($p<0.001$ for interaction disease course x country). In Sweden, QoL was better in relapsing patients while in Germany and Poland progressive patients performed better in the QoL scores.



Proportion of PwMS that are employed (with confidence intervals) stratified by disease course and country [GER = Germany, POL = Poland, SWE = Sweden]

Logistic regression analysis showed substantial differences between countries ($p<0.001$) and also a substantial interaction between country and disease course ($p<0.01$).

Conclusions

The first results of this EUReMS test study show that it is feasible to collect, merge and analyze PRO data in a considerable number of PwMS on a European level, and to compare QoL and employment in selected European countries.

With the final results of the ongoing analysis, the consortium will be able to improve processes and tools for the integration and comprehensive analyses of PRO data from different sources across Europe which ultimately will help to compare and harmonize the health care situation of PwMS across Europe.

EUReMS Consortium

Data providers for PRO1 Study

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Disclosure

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A Tool To Assess, Compare And Enhance The Status Of People With MS
Throughout the European Union
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