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Abstract:

**Background:** The value of MS registry information is increasingly recognised and a structured description of this data will facilitate analysis and comparisons of the data.

**Objective:** The overall aim was to create an overview of the MS registry landscape by updating and expanding a previous study of identifying and describing MS registry data currently collected in Europe.

**Methods:** We approached identified MS registries and requested their participation in the study by filling in an extensive survey.

**Results:** Nineteen surveys were completed and returned. The main aim and focus of the different registries vary considerably as does the number of MS patients and inclusion criteria. Most registries collect data within common general categories although there are more pronounced differences regarding specific subcategories.

**Conclusion:** Information on data collected by European MS registries is essential for large international projects. Such efforts involve large amounts of harmonised data and depend on functional technical solutions as well as regulatory requirements to allow individual registries to contribute data in a manner, which complies with local and national requirements.

Keywords: multiple sclerosis, registries, mapping survey

Introduction:

Multiple sclerosis (MS) is a chronic inflammatory and neurodegenerative disease of the central nervous system which affects 2.5 million people worldwide (1). There are significant geographical differences with the highest prevalence occurring in Northern Europe and North America (over 100/100,000) as compared to 2/100,000 in Japan (2, 3). MS patients are typically diagnosed between the ages of 20 and 50 years (4) and will in most cases be expected to live for a long time with MS (5). Although the treatment options have improved dramatically over the past decades, health care regulations and treatment strategies vary significantly between different countries (6).

The value of MS registries for MS patients, health care providers and regulators is becoming increasingly recognised (7). The collection of patient data into a registry can benefit the patients by enabling the clinician to prospectively follow the individual patient concerning disease progression, treatment response and side effects, and other parameters including patient reported outcomes (PRO) measures (8). From a societal viewpoint there are also many advantages of using data from MS registries, especially within areas of epidemiology and treatment studies, such as post marketing
effectiveness, comparative or post-authorisation safety studies (9). This was recognised by regulatory bodies in the EU resulting in the first EMA-Workshop on MS-Registries in July 2017 in London (10). Therefore it is important to improve and promote the collection of safety data by MS registries as this might provide an opportunity for the MS registries to replace the typical drug specific post-authorization safety studies (11). National or regional MS registries could represent the foundation on which to develop larger scale important asset of data for different stakeholders (12). If the appropriate study designs and a common data set can be agreed upon, MS registries may offer an excellent source of data in order to ultimately address the topic of how to provide the best and most cost effective care model for persons with MS (PwMS) and to monitor treatments safety. Sub-group registries such as the German registry on pregnant women with MS can provide further valuable insights (13).

In our previous survey (14), 13 European MS registries were described. The current study was performed to update and expand the knowledge of the MS registry data and includes 19 MS registries, all based in Europe, with the exception of the international MSBase (15).

**Materials and Methods:**

*Identification of MS registries and databases:* We approached the 13 MS registries that participated in the 2014 study by Flachenecker et al (14) and received completed survey responses from 12 of them. We contacted a further 12 MS registries which had been identified by the European Multiple Sclerosis Platform (EMSP) (16) and received completed surveys from eight of them. Subsequently, the results of the Liguria MS register survey were incorporated with those of the Italian MS register, reducing the total number of registries to 19.

*Development of survey:* The survey was based on the previous questionnaire used in the 2014 study (14) and further modified with additions from the MS Registry Advisory Board pre-meeting survey (S1) as well as questions considered relevant by the authors for collecting information on registry data. The survey included questions on organisational aspects, background/purpose, inclusion criteria, documentation process, data collection, quality control, governance, and the status of the registry as of January 31, 2017. The survey questions on data collection incorporated personal data, clinical categories, patient derived measures and additional categories including co-morbidities, socioeconomic and societal services and healthcare utilization. The contact persons of the registries were asked to report if data is collected (yes or no). The registries were also asked to indicate if filling in data is mandatory or optional as well as to provide data counts on the different variables, if available. The original questionnaire has been included as supplementary information (S2).

*Distribution of survey:* Representatives of the MS registries were contacted by email enclosing a cover letter and the survey. The senders of the letter were representatives of Karolinska Institutet (AG and JH), Swedish MS registry (JH), EMSP (CT), MS Registry DMSG (AS), OFSEP (SV and ACG), Sana Kliniken (PF), University of Goettingen (OR and TM), Italian MS Society (GB and PZ) and University of Ferrara (MP). The registries, which had earlier responded in above mentioned surveys, were presented with a partly pre-filled form with their previous answers in order to facilitate their participation. They were instructed to review and update the pre-filled information. The registries, which had not participated in previous surveys, were sent a clean version of the survey.
Reminders and follow up questions: The contact persons of each registry received at least one email reminder if they failed to respond the first time. Representatives of registries who completed the survey were re-approached regarding their availability for follow up questions. We interviewed nine of the registry representatives by phone, nine via email and one was interviewed in person. Interviews were aimed to further explore the registry-funding situation and how governance and involvement in scientific collaborations was regulated. There were also interview questions regarding missing information in the survey and potential overlaps with other registries.

Analysis of the results: The results of the surveys were analysed and summarized. Due to missing data collection information, resulting in the total number of responding registries varying between 16 and 19 (Tables 3-6), the results are presented as the number of registries collecting data compared to the total number of responding registries.

Results:

Nineteen MS registries agreed to participate in our survey (Table 1). Although we initially also approached MS registries outside Europe, all the registries which responded to our survey are based in Europe with the exception of MSBase which includes patient records from 33 countries and whose administrative offices are based in Australia (15). Most of the registries are national although there is at least one regional registry (Catalonia) (17, 18). In addition there is one national sub-group registry (DMSKW - a German pregnancy registry) (13). Four European or US MS registries did not reply or did not return the survey results.

The results of the survey revealed that 10/18 (56%) of registries reported that an academic/research institution was keeping the registry followed by 4/18 (22%) kept by patient organisations and 3/18 (17%) by health care organisations. Three registries were from “non-profit organisations” and one from “association of research centres”. One registry did not report organisation information and some of the registries reported more than one organisation keeping the registry (Table 1).

The number of patients included in the participating MS registries covers a wide range, from around 1000 to 50,000 PwMS. However, information about the prevalence of individual countries was not included in the present survey. There are known overlaps of patients between some of the registries but the extent of such overlaps is difficult to estimate. Some registries were started more than 50 years ago and some very recent which might also reflect the size of the registries (Table 1).

All the registries report that they include patients according to McDonald criteria, while 10 registries additionally include patients based on Poser criteria. Thirteen registries also include possible MS/CIS patients that are not fulfilling McDonald/Poser criteria, and four registries include patients with self-reported MS without clinical validation. Seventeen registries reported including centres with any number of PwMS whilst one registry reported that a minimum number of MS patients within a centre is required in order to be included (Table 2).

In the general categories of personal data, basic disease and treatments, data are collected by all registries (Table 3). Clinical data on disability by Expanded Disability Status Scale (EDSS) is collected by 18 of the responding registries, whilst other disability measures are less frequently collected (Table 4). Cognition scales are only recorded by 9/19 (47%) of the registries (Table 3) where the most commonly reported scales are the Symbol Digit Modalities Test (SDMT) and Paced Auditory Serial
Addition Test (PASAT3), reported by 7/18 (39%) and 6/18 (33%) of the registries, respectively (Table 4).

Information on treatments was included in the survey for relapse therapy, disease modifying treatments (DMTs) and symptomatic treatments. Relapse therapy is collected by 15/18 (83%) of the registries. All registries reported data on DMTs, with 17/19 (89%) of the registries collecting data on current DMTs. Medical current symptomatic treatment is collected by 11/18 (61%) of the registries (Table 4).

MRI data (yes or no) is reported by 16/19 (84%) of the registries, although the type of MRI data varies between registries and only 2/18 (11%) have reported collecting data on brain volume (Table 3 and 4).

Para-clinical data is collected by 14/19 (74%) of the registries and most frequently as information on cerebrospinal fluid (CSF) analysis of cells and intrathecal IgG production, which is collected by 13/19 (68%) as well as evoked potentials/visual evoked potentials by 10/19 (52%) (Table 4).

The number of registries that collect information on patient derived measures is generally lower than for the clinical categories. MS Impact Scale (MSIS-29) data is collected by 7/18 (39%) of the registries and represents the most commonly collected outcome measure in this category. Information about depression is collected by 5/18 (28%) and fatigue by 6/19 (32%) of the registries. Fatigue is further explored in the survey by questions on six different fatigue scales but only two, Krupps’ Fatigue Severity Scale (FSS) and the Modified Fatigue Impact Scale (MFIS) are reported to be recorded by any of the MS registries (Table 5).

The survey also covered additional categories such as co-morbidities where chronic diseases and co-medication were reported by 13/19 (68%) and 10/19 (53%) of the registries, respectively. There were also questions related to socio-economy included in our survey such as occupation, employment and education, recorded by 12/17 (71%), 14/19 (74%) and 12/19 (63%) of the registries, respectively. In addition, 6/18 (33%) of the registries reported collecting other socio-economic data (Table 6).

Information on mandatory/optimal data entries was provided by most of the registries at least for some categories. Data counts for a significant number of variables was provided by six registries (MSBase, OFSEP, MS-Register der DMSG (Bundesverband e.V.), the Italian MS Register, the Swedish Neuro Registries-MS and the UK MS Register). As this information was not provided by more registries, we have not incorporated this information in the results.

The survey also included questions related to quality control strategies applied by the registries. Although only 10 registries specifically reported having a manual and/or automatic quality control mechanism, all registries except one, reported using some quality control system. Ten registries reported control of coverage of data-supplying centres and 10 registries reported control of representativeness of the population within the centres. The most common trigger for data entry was “Patient visit in data-supplying centre” which was reported by 15 registries (Table 7).

The results from the questions regarding funding showed that five registries reported receiving public funding, whilst seven received support from industry. Non-profit funding was reported by 12 registries and four reported other funding. Some registries reported more than one source of funding. Although five and 11 registries reported being very confident or fairly confident about future funding, four registries reported being not confident at all (Table 8a).
Approval by data protection authorities and ethic committees had been required for 12 and 14 registries, respectively. Informed consent was used by 16 registries and in 15 in the form of written informed consent. Access to data was regulated by all the 18 registries which responded to this survey question (Table 8a).

We carried out follow up interviews mainly focused on funding and governance with all of the 19 MS registries, which in general confirmed the previous survey responses and provided further details especially regarding future funding and requirements needed to be met in order to carry out scientific collaborations. Although some, such as OFSEP, and the Danish and Italian MS registries, reported continued funding pending favourable evaluations on a regular basis, other registries had a less structured funding plan and two of the registries had no specific funding and were thus dependent on voluntary contributions. Scientific collaborations were generally welcomed by the MS registries but access to data for research purposes typically needed to be approved by local and/or national authorities (Table 8b).

Discussion:

The previous MS registry mapping survey from 2014 (14) was able to identify and describe the national MS registries in 13 European countries. With the present study, which includes 19 MS registries, we aim to give an informative and updated overview of the MS information currently collected in Europe. This could provide a useful basis towards further efforts at combining and harmonizing data from MS patients in order to carry out larger and statistically more powerful studies than what is possible on a national or local level. There are examples of international collaborations such as the European Register for Multiple Sclerosis (EURREMS) (14, 19) which was an EU funded collaboration of MS registries focussed on epidemiology and treatment studies and Big MS Data (BMSD) which is a collaborative effort, initiated in 2014, between OFSEP, the Danish, Italian and Swedish MS registries and MSBase.

MS registries are often used in a clinical setting where registry data can assist the physician by making information on individual patients easily accessible. Such information can include data from access to health care services as well as a comprehensive overview of treatments, clinical procedures and other types of data about the patient. Many registries also focus on data which can be used for research purposes such as epidemiology, treatments effectiveness and safety and PROs. Patient derived measures have attracted increasingly more attention in the past few years, hence some of the registries are especially focussed on patient advocacy often involving an MS society or patient organisation. Patient organisations and MS societies report how MS patients often can and want to be involved in the management of their disease.

The questions on socio-economy would likely be interpreted to refer to information directly available from the MS registries. This would therefore typically not include the way in which, in some countries, socio-economic information from public registries can be independently linked to data from patient registries as part of specific research projects requiring local ethics board approvals.

The reported information from MS registries in this report can provide a valuable description of potentially available data on a significant part of up to approximately 700,000 PwMS in Europe (20, 21). Our study shows which categories of data are being collected but does not specify the number of data counts. The survey format did offer the possibility of reporting number of data counts per category but as many registries did not provide this information was not included in the summarized
report. Furthermore, given the differences in the numbers of patients and the frequency of data collections, the amount and likely also the quality of collected data points varies significantly between registries and is difficult to estimate. For any potential future international collaboration, the issue of how to harmonise data from MS registries in the most optimal way with differences in patient inclusion criteria, collection frequency, quality control strategies and collected data categories as well as potential patient overlap between registries, will need to be given careful consideration.

A mapping of the information that is collected by individual registries and their interest in and availability towards international collaborations is a useful starting point for endeavours of combining and harmonizing large sets of data from MS patients. The BMSD project has managed to harmonise datasets from over 100,000 MS patients and the results are currently being analysed. In addition to the growth of patient registries for scientific and clinical purposes, registries are receiving increased attention and support by MS Societies for their role in decision-making processes. Such long-term “real world evidence” data will also be of interest to pharmaceutical companies and regulatory bodies. However, any attempts at carrying out projects involving pooling large sets of data on MS patients or standardized analysis within the individual MS registries, will need to be carefully monitored and approved by both local and national authorities in order to ensure that data access and handling complies with national, international and ethical regulatory requirements.

In conclusion, the number of MS patients in Europe is estimated at 500,000-700,000. We have identified 19 MS registries all based in Europe with the exception of the international MSBase and described the data collected by these registries that could provide a basis for the analysis of large amounts of data from MS patients.

Tables

Table 1. Features of 19 MS registries
Table 2. Inclusion criteria
Table 3. Data collected
Table 4. Clinical categories
Table 5. Patient reported outcomes
Table 6. Additional categories
Table 7. Quality control
Table 8a and 8b. Funding and governance/Follow up questions

Supplementary information

S1 Merck questionnaire
S2 Questionnaire (2017)
References

Affiliations / Disclosures

AG Department of Clinical Neuroscience and Centrum for Molecular Medicine at Karolinska Institutet, Stockholm, Sweden.

AS MS-Register of the German MS-Society, MS Forschungs- und Projektentwicklungs-gGmbH, Hannover, Germany.

TMe University Medical Center Göttingen, Department of Medical Informatics, Göttingen, Germany.

PF Neurological Rehabilitation Center Quellenhof, Bad Wildbad, Germany.

DH Department of Neurology and Center of Clinical Neuroscience, First Faculty of Medicine, Charles University and General University Hospital in Prague, Czech Republic.

PZ Scientific Research Area, Italian MS Society, Genoa, Italy. / No conflict of interest

MP Dept. of Biomedical and Surgical Sciences, University of Ferrara, Italy, S. Anna University Hospital, Via Aldo Moro 8 - 1C3, 44124 Ferrara (FE), Italy.

OR University Medical Center Göttingen, Department of Medical Informatics, Göttingen, Germany.

SV 1 Service de Neurologie, sclérose en plaques, pathologies de la myélite et neuro-inflammation, and Observatoire Français de la Sclérose en Plaques, Hôpital Neurologique Pierre Wertheimer, Hospices Civils de Lyon, Lyon, F-6977, France; 2 Centre des Neurosciences de Lyon, INSERM 1028 et CNRS UMR5292, Lyon, F-69003, France.

3 Université Claude Bernard Lyon 1, Faculté de Médecine Lyon-Est, Villeurbanne, Auvergne-Rhône-Alpes, F-69622, France.

ACdg1 Observatoire Français de la Sclérose en Plaques, Hôpital Neurologique Pierre Wertheimer, Hospices Civils de Lyon, Lyon, F-6977, France; 2 Université Claude Bernard Lyon 1, Faculté de Médecine Lyon-Est, Villeurbanne, Auvergne-Rhône-Alpes, F-69622, France.

MAB 1. Department of Life Sciences, University of Siena, Italy; 2. Italian MS Foundation, Genoa, Italy.

WB Department of Neurology, Specialist Hospital, Końskie, Poland, and The Faculty of Medicine and Health Science, Institute of Physiotherapy, Jan Kochanowski University, Kielce, Poland.
Department of Neurology, The Royal Melbourne Hospital, Melbourne, VIC, Australia/Department of Medicine, The University of Melbourne, Melbourne, VIC, Australia/Department of Neurology, Box Hill Hospital, Monash University, Melbourne, VIC, Australia.

Eugène Devic EDMUS Foundation against Multiple Sclerosis and Observatoire Français de la Sclérose en Plaques (OFSEP), Hôpital Neurologique Pierre Wertheimer-GHE, Hospices Civils de Lyon, F-6977, France.

Clinic of Neurology, CCS, Faculty of Medicine, University of Belgrade, Belgrade, Serbia.

MS-Register of the German MS-Society, MS Forschungs- und Projektentwicklungs-gGmbH, Hannover, Germany.

Department of Basic Medical Sciences, Neurosciences and Sense Organs, University of Bari "Aldo Moro", Italy.

Neurology, Departments of Medicine, Biomedicine and Clinical Research, University Hospital Basel, University of Basel, Switzerland.

Department of Clinical Neuroscience, Karolinska Institutet, Stockholm, Sweden

The Danish Multiple Sclerosis Registry, Department of Neurology, Rigshospitalet, University of Copenhagen, Denmark.

Department of Clinical Medicine, University of Bergen, and The Norwegian MS-Registry and Biobank, Department of Neurology, Haukeland University Hospital, Bergen, Norway.

The Greek Multiple Sclerosis Society, Thessaloniki, Greece and Aristotle University of Thessaloniki, Greece.

Aristotle University of Thessaloniki, Greece.

Preventive Medicine and Epidemiology Department. Hospital Universitari Vall d’Hebron, Universitat Autònoma de Barcelona, Barcelona, Spain (2) Department of Neurology / Neuroimmunology, Multiple Sclerosis Centre of Catalonia (Cemcat), Hospital Universitari Vall d’Hebron, Universitat Autònoma de Barcelona, Barcelona, Spain.

Institute of Epidemiology, Faculty of Medicine, University of Belgrade, Serbia.

Department of Neurology / Neuroimmunology, Multiple Sclerosis Centre of Catalonia (Cemcat), Hospital Universitari Vall d’Hebron, Universitat Autònoma de Barcelona, Barcelona, Spain.

Department of Neurology, CHU Charleroi, Lodelinsart, Belgium.

Division of Clinical Neurosciences, Turku University Hospital and University of Turku, Turku, Finland.

Department of Clinical Neuroscience, Karolinska Institutet, Stockholm, Sweden

Department of Basic Medical Sciences, Neurosciences and Sense Organs, University of Bari, Italy.

Department of Neurology, MS Center Dresden, Center of Clinical Neuroscience, University Hospital Carl Gustav Carus, Dresden University of Technology.

Department of Clinical Neuroscience and Centrum for Molecular Medicine at Karolinska Institutet, Stockholm, Sweden.

European Multiple Sclerosis Platform (EMSP), Schaerbeek, Belgium.
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PZ?
Pietro Iaffaldano has served on scientific Advisory Boards for Biogen, Teva, Merck Serono, Novartis and Roche; has received speaker honoraria from Biogen Idec, Sanofi-Aventis, Merck Serono, Novartis, Roche, Sanofi, Genzyme and Novartis.

E
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TMa ?

RM?
Kjell-Morten Myhr reports unrestricted grants and/or scientific advisory board or speaker honoraria from Almirall, Biogen, Genzyme, Merck, Novartis, Sanofi-Aventis, Roche, and the Norwegian MS Society outside the submitted work.

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CT?

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