



EUROPEAN
MULTIPLE SCLEROSIS
PLATFORM

Can Real World Data advance Equity of Health Care in Europe?

EVENT REPORT



Tuesday, 7 March 2017
European Parliament, Brussels

OBJECTIVE OF THE MEETING

People with Multiple Sclerosis living in the European Union could receive timelier access to safer and more efficient therapies and could become important partners in both the regulatory and the *Health Technology Assessment* processes of medicines. The key to turning these possible scenarios into reality is the better exploitation of so-called “Real World Evidence” (RWE) data. This was the main conclusion of a European Parliament debate co-organised by the European Multiple Sclerosis Platform (EMSP) and MEP Cristian Buşoi (EPP) on 7 March 2017.

The organisers proposed a pressing question to the multi-stakeholder attendance: **“Can Real World Evidence Data Advance the Equity of Health Care?”**

We need better data for better outcomes!

"There are no more doubts on the potential outcomes and benefits of data collection systems: being made fit for purpose, they could support more patient-relevant MS research through patient reported outcomes, allowing the emergence of better treatments and therapies for people with MS. MS data collection systems across Europe have been evolving over the last years and new registries were created but we need to encourage Member States to continue strengthening this approach. We can only do that by raising awareness among policy and decision makers of the potential and benefits of patient data and also by encouraging the European Commission to make more public funding available for this. At the moment, the lack of public funding for the existing registries threatens their long-term sustainability".

EMSP External Affairs Director, Christoph Thalheim

OPENING

Being the host of the event, **MEP Cristian Buşoi** welcomed the participants and **reinforced the role policy makers play in the improvement of lives of people with multiple sclerosis and other chronic conditions.**

MEP Buşoi highlighted the contribution that quality data can make towards early diagnosis, informed treatment decisions and allocation of research funding in the area of multiple sclerosis.

*"The question in the title of the panel discussion is: **Can Real World Data Advance the Equity of Health Care in Europe?** I believe it should drive us to reflect first and foremost at the use of data in the benefit of patients. Yes, I do agree that we need caution when using and giving medical data, but time has shown us through the electronic health record and chronic disease databases that this can be helpful and in the benefit of patients.*

The objective of our meeting today is to set out the importance of real world evidence data in public health care".

MEP Cristian Buşoi



Time matters: the “Brain Health” policy initiative driven by health care providers, health economists and patient advocates

Brain health

A guide for people with multiple sclerosis

George Papageorgiou
Harald Reichert
Tobias Klockner
Gavin Giovannoni
Eva Herberich
Jeremy Robert
Janis Klockner
Maria Pia Simioni
Christoph Thiele
Antonio T. M. Monteiro
Tobias Klockner



The first part of the event discussed the importance of early diagnosis and flexible treatment in preserving brain and spinal cord tissue early in the disease.

The policy report “Brain Health: time matters in MS” was used as starting point for the discussion. *“Even in the early stages of multiple sclerosis, cognition, emotional well-being, quality of life, day-to-day activities and ability to work can be markedly affected by the damage occurring in the brain and spinal cord. As the disease progresses, increasing disability – such as difficulties in walking – imposes a heavy burden on people with multiple sclerosis and on their families”.*

Early effective treatment can preserve ‘brain health’

MS neurologist **Gavin Giovannoni**, lead author of *Brain health: time matters in multiple sclerosis*, gave a sobering description of the potential progression towards disability for someone with poorly managed MS – at the most severe stage of disability, quality of life may be considered ‘worse than death’. *“We all lose brain volume as we age, but brain loss is accelerated in people with MS. Provision of early, effective treatment, however, can help to slow this decline and preserve brain health.”*

Responsibility for speeding up the delivery of health care and protecting the brain lies with us all: the person with MS, health care professionals, health care systems, regulators and politicians.”



Early intervention makes economic sense

Health economist **Gisela Kobelt** presented results from a [recent study](#) into the burden and cost of MS involving almost 17,000 patients from 16 European countries. The costs of illness increased, on average, five-fold between mild and severe MS. Most study participants (95%) complained of fatigue and 70% had overwhelming cognitive difficulties. These symptoms start early in the disease course and may explain why many people with MS stop working before they experience physical impairment.

"Around 30-40% of patients of working age are not working due to MS." Not surprisingly, as the disease progresses and disability increases, quality of life decreases and costs increase, in particular costs to society. Dr Kobelt concluded, therefore, that **"from an economist's perspective, the results of the study point to the importance of early intervention."**



Dr Gisela Kobelt



Dr Maura Pugliatti

Data from registries can fill gaps in our knowledge

"MS registries can provide an opportunity to collect MS data from several countries in a uniform way", neurologist **Maura Pugliatti** explained.

The European Registry for Multiple Sclerosis (EUREMS) – a project coordinated by EMSP and co-funded by the European Commission – achieved a proof of concept on harmonization of data collection between 2011 and 2014. Gaps remain in our knowledge, though, and there is a need for a European Network of MS Registries that would facilitate minimal data sets from research funding bodies, regulators, health care payers, pharmaceutical companies and patient advocacy groups.

At present, only a third of European patients receive the medication or therapy needed."Real world data can gather evidence which can fuel health care interventions and support the development of improved models of health care."

'Real world evidence' helps regulators make decisions

Xavier Kurz, Head of Surveillance and Epidemiology at the European Medicines Agency, listed some methods for collecting 'real world' data, that is, data obtained outside the constraints of randomized clinical trials.



Such data can help with decisions about a wide range of treatments, for example:

- What are the long-term health benefits, compared with the standard treatment?
- Does vaccination control the spread of infection?
- Where is this drug being prescribed, and how many deaths are linked with its use?

In the long term, *good real world evidence can help to improve the development and subsequent use of drugs (including better assessment of their efficacy and safety); it also provides a stronger basis for decisions by regulators and reimbursement agencies.*

Disability is expensive: long-term data helps payers make decisions

Are long-term data on MS really needed? **Eva Havrdová** (representing ECTRIMS, the European Committee for Treatment and Research in MS) maintained that some important questions cannot be fully answered without better data, for example:

- How have disease-modifying treatments changed the course of MS?
- How does early treatment influence the development of disability, compared with later treatment?
- Does early treatment escalation change the prognosis, compared with late escalation?

One thing we do know: **disability costs money**, in terms of healthcare, late-stage care, disability pensions, loss of GDP and lost quality of life. Payers need to base their decisions on data from clinical studies (which leads to registration of drugs) and on real world data.

Can we trust real-life data ?

YES, IF:

- data quality is regularly checked
- motivation of those entering the data is kept
- each subject understands the meaningfulness of the registry (e.g. change in health care occurs based on the data)

= financing is solved

Dr Eva Havrdova

A move is needed from Disease Registries to Patient Registries

Francois Houyez, Director of Treatment Information and Access at EURORDIS, gave an HTA perspective and started with introducing the reality of patients registries vs what patients expect from them

Registers vs Patients: aims of a register

<i>Register reality</i>	<i>Patient expectations</i>
1. Epidemiological research	1. Healthcare/Social Services planning
2. Clinical research	2. Treatment evaluation (efficacy/safety)
3. Natural history of the disease	3. Natural history of the disease
4. Disease surveillance	4. Epidemiological research
5. Treatment evaluation (efficacy/safety)	5. Clinical research
6. Genetic mutations database	6. Disease surveillance
7. Healthcare/Social Services planning	7. Genetic mutations database

Real world evidence data is important for regulators and payers as **indicators for measuring health care intervention outcomes.**

Why are Disease Registries important?

- To ensure that patients are fully instructed in the proper use of medicines
- To align the interests of inventor firms with those of patients and the generic drug producers — interests that currently are diametrically opposed

The debate also allowed representatives of patient organisations, regulators, health care providers and HTA bodies to discuss how real world can become the co-driver of regulatory and reimbursement decisions.

A commonly accepted scenario was that it could **reduce the costs incurred by health care systems and improve access to medicines.**



CALL TO ACTION

Real world evidence data has the potential to:

1. **Enable innovation** through a better understanding of treatment outcomes
2. Identify and assess potential **safety issues**
3. Determine **efficacy and patient relevance of existing therapies**
4. **Enlarge and enrich the (data) base for EMA** and /or payer decisions
5. **Optimise the use of medicines** through ongoing monitoring
6. **Reduce the costs of the healthcare systems** and improve access to medicines

EMSP, as the main voice of people with MS in Europe, CALLS for more public funding available for the set-up and maintenance of disease specific patient registries.

Temporary pooling and comparing of patient data from independent registries in different countries will be of great benefit to MS patients' advocacy work and can be applied to other diseases as well. With our push for a **European Network of National MS Patient Registries** we wish to encourage a growing number of MS registries to **adopt the same protocols of data pooling and analysis** for all those cases, where national data collection is insufficient.

The analysis of « real life » patient data on European level can provide some of the key answers required by, regulatory bodies, health care payers, medical researchers and patient advocates.

Christoph Thalheim, EMSP



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Raising the voice of people with MS in Europe