Background

- Diagnostic criteria, treatment options, monitoring procedures and our understanding of multiple sclerosis (MS) are rapidly evolving.
- Relapsing MS is no longer considered to consist solely of episodic attacks on myelin in the central nervous system (CNS); diffuse damage to white and grey matter is ongoing throughout the disease course.
- To compensate for damage, the brain appears to have a neurological reserve - a finite capacity to re-route signals or adapt undamaged areas to take on new functions.

Objective

- To develop international consensus recommendations for improving diagnostic, management and access to treatment in MS based on advances in disease understanding.

Methods

- An international working group comprising clinicians, researchers, specialist nurses, health economists and representatives from patient groups conducted structured discussions during 2015 to examine:
  - the personal and economic impact of MS
  - current practice in diagnosis, treatment and management of MS
  - definitions of disease activity
  - barriers to accessing disease-modifying therapies (DMTs).

Policy recommendations

- The resulting recommendations for policy change (Figure 1) have been widely endorsed by professional organizations and patient groups.

1. Speed up referral and diagnosis

- Significant delays often occur before a person with symptoms suggestive of MS sees a neurologist. Improved access to MS healthcare professionals and services is therefore required.
- Neurologists with interest and expertise in MS are the healthcare professionals best placed to provide routine diagnosis and to establish an integrated multidisciplinary approach to special care and management.
- Campaigns are needed to raise public and professional awareness of MS and the detrimental effect on brain health of delays in diagnosis and treatment.

2. Intervene early to maximize lifelong brain health

- Cognitive impairment in early MS reduces quality of life, daily functioning and employability.
- Preserving brain volume and cognitive reserve (the two components of neurological reserve) protects against disease-related cognitive decline and disability progression.23 24
- A delay in diagnosis may lead to a failure of neuromodulation, cognitive function and physical function by reducing disease activity in order to preserve CNS tissue.
- Using the lag time prior to diagnosis to describe neurological reserve can help people with MS to conceptualize their disease.
- Start treatment early, with DMT and lifestyle measures.

Figure 2. Monitoring is crucial to identifying treatment failure and enabling timely switching to a different DMT.

4. Act swiftly and generate evidence

- Act swiftly on suboptimal control of disease activity by considering switching to a DMT with a different mechanism of action.
- Generate real-world evidence from registries about the long-term effectiveness and safety of DMTs and therapeutic strategies for use by regulatory authorities, technology appraisers, payers and healthcare professionals.

Figure 3. The proportion of people with all forms of MS receiving a newer DMT in 2013 varied considerably between countries.

5. Take a comprehensive economic approach to evaluating treatment cost-effectiveness

- Costs - especially indirect and informal care costs - increase significantly as disease progresses.25
- The recommended therapeutic strategy (Figure 1) has the potential to reduce disability progression and avoid some of these long-term costs.
- In many jurisdictions, however, access to DMTs is limited. In 14 upper-middle and high-income countries, the proportion of people with MS receiving a DMT in 2013 was in the range of 13-69%.
- To improve access to treatment, the relevant bodies should consider all costs to all parties when conducting economic evaluations, not just those borne by healthcare and social services.
- The continuing investigation, development and use of cost-effective therapeutic strategies and alternative financing models should be encouraged.

Conclusions

- Major policy changes are needed in order to translate advances in diagnostic criteria, monitoring procedures and disease understanding into better outcomes.
- The overarching recommendations below aim to facilitate a therapeutic strategy that is consistent with the latest evidence, shared decision-making, and improved treatment access.
- Optimize the diagnosis of MS and in the time to treatment initiation.
- Set goals for treatment and ongoing management that will optimize outcomes for every person with MS.
- Consider the most robust evidence base possible when making treatment and management decisions.
- Formally record the results of monitoring to generate further real-world evidence.
- This more urgent approach will enable MS healthcare professionals and other stakeholders to strive towards the highest possible standards of care.

To read the full report and consensus recommendations, visit www.msbrainhealth.org

References

4. Gladek W et al. 2010;75:8–6


Gavin Giovannoni,1 Helmut Butzkueven,2 Suhayl Dhib-Jalbut,3 Jeremy Hobart,4 Gisela Kobelt,5 George Pepper,6 Maria Pia Sormani,7 Christophe Thalhammer,8 Anthony Traboulsi,9 Timothy Vollmer10

Abstract

A growing body of evidence supports early treatment in people with multiple sclerosis (MS) to help prevent irreversible damage and functional loss. However, this requires an accurate and timely diagnosis and early treatment. Diagnostic criteria, definitions of disease activity, and treatment options continue to evolve. Access to disease-modifying therapies (DMTs) varies considerably between countries, and the importance and economic impact of these treatments has increased. To address these issues, a group of international experts was convened to consider the evidence for early treatment, diagnostic criteria, definitions of disease activity, and treatment options. The overarching recommendations below aim to facilitate a therapeutic strategy that is consistent with the latest evidence, shared decision-making, and improved treatment access. 

MS Brain Health Time Matters

Figure 1. We recommend a therapeutic strategy based on regular monitoring that aims to maximize lifelong brain health while generating robust real-world evidence. DMTs: disease-modifying therapies.

Figure 2. Monitoring is crucial to identifying treatment failure and enabling timely switching to a different DMT.

Figure 3. The proportion of people with all forms of MS receiving a newer DMT in 2013 varied considerably between countries.

Disclosures

- Giavannoni has received consulting fees from AbbVie, Bayer, Biogen, Celgene, Genzyme, GSK, Novartis, Roche, Sanofi and Teva, and has received grants/research support from Bayer, Biogen, Genzyme, Novartis and Oxford. Dr. Giovannoni has also received consulting fees from Biogen, Genzyme, Merck Serono, and Oxford, and has received grants/research support from Bayer, Biogen, Genzyme, Merck Serono, Oxford, and Novartis. Dr. Butzkueven has received consulting fees from Acorda, Avanir, Biogen, EMD Serono, Genzyme, Janssen Research & Development, MedImmune, NIH/NINDS, Ono, Rocky Mountain MS Center and Teva.
- Dr. Dhib-Jalbut has received consulting fees from Bayer, Genentech, Genzyme, Oxford PharmaGenesis, Serono and Teva; and has received grant/research support as a PI on clinical trials with Biogen, Chugai, Genzyme and Roche. T Vollmer has received consulting fees from AbbVie, Biogen, Merck Serono, Novartis, Oxford PharmaGenesis, Sanofi Genzyme and Teva. G Pepper has received consulting fees from Biogen, Novartis, Oxford PharmaGenesis and Teva. MP Sormani has received consulting fees from Bayer, Genentech, Genzyme, Oxford PharmaGenesis, Serono and Teva; and has received grant/research support as a PI on clinical trials with Biogen, Chugai, Genzyme and Roche. J Hobart has received consulting fees, honoraria, grants and professional fees from Acorda, Acorda, Genzyme, Janssen Research & Development, Merck Serono, Novartis, ONO, Oxford PharmaGenesis, Serono and Teva. G Kobelt has received consulting fees from AbbVie, Biogen, Genentech, Genzyme, Merck Serono, Novartis, Ono and Teva, and has received grants/research support from Bayer and Teva. G Kobelt also has received grants/research support from AbbVie, Biogen, Genentech, Genzyme, Merck Serono, Novartis and Oxford and has received grants/research support from Bayer and Novartis.
- The authors declare no competing interests.

Preparation of the report and the recommendations was funded by an educational grant from AbbVie to Professor Giovannoni.

Prepared at the 17th Annual Meeting of the Brazilian Committee for Treatment and Research in Multiple Sclerosis (CETRIMS), June 22–26, 2015, São Paulo, Brazil.