Brain health: time matters in multiple sclerosis – developmental process and objectives of international consensus policy recommendations

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Background

- Disease understanding, diagnostic criteria, treatment options and monitoring procedures in multiple sclerosis (MS) are rapidly evolving.
- Major policy changes are needed, however, in order to translate these advances into improved outcomes.
- Achieving lasting change requires the support of many groups, including patient organizations, healthcare professionals, policy makers, payers and bodies that conduct health technology appraisals (HTAs).

Objectives

- To describe the development of consensus policy recommendations on diagnosis, therapeutic strategies and improving access to treatment in MS.
- To outline the strategy for global dissemination and implementation of these recommendations.

Methods

- A literature survey guided by the lead author of the report (Professor Giovannoni) and supported by professional medical writers examined:
  - current practices in diagnosis, treatment and management
  - definitions of disease activity
  - barriers to accessing disease-modifying therapies (DMTs)
  - personal and economic impacts of MS.
- A report containing policy recommendations was developed by multidisciplinary author and working groups comprising clinicians, researchers, specialist nurses, health economists and representatives from patient organizations.
  - The author group (10 people) developed an outline, participated in structured consensus conferences on March 2 and May 22, 2015, reviewed and contributed to all four drafts and approved the final report.
  - The working group (14 people) participated in the second conference and contributed to two drafts and the approval version.
- The report, *Brain health: time matters in multiple sclerosis*,[1] was published on October 6, 2015.
  - This marked the public launch of the ongoing MS Brain Health initiative (**Figure 1**).[2]

Results

Therapeutic strategy

- The report recommends a clear treatment goal: to preserve central nervous system tissue and maximize lifelong neurological reserve by reducing disease activity.
- A therapeutic strategy based on proactive monitoring and shared decision-making will help to achieve this. Early diagnosis, improved access to DMTs and generating real-world evidence are also key components (**Figure 2**).
- Enabling and promoting widespread adoption of this therapeutic strategy has the potential to improve outcomes for people with MS.

Policy recommendations

- The policy recommendations that aim to facilitate the therapeutic strategy are grouped under three overarching recommendations.
  - Minimize delays in 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.
  - Consult the most robust evidence base possible when making treatment and management decisions.
- Each of 18 individual recommendations is directed towards at least one of: clinicians, specialist nurses and their professional bodies; patient organizations; healthcare providers; HTAs; reimbursement agencies; insurance carriers; regulatory authorities; pharmaceutical companies; and curators of registries and databases.
- Access to DMTs varies widely across Europe (**Figure 3**)[3–6]; barriers include licensing and national guidelines.
  - The European Medicines Agency (EMA) has excluded some newer DMTs from initial use in most people with relapsing–remitting MS.[7,8]
  - Compared with the licence issued by the EMA, national reimbursement guidelines in several countries place greater restrictions on the circumstance under which a particular newer DMT will be funded.[3]
- The following recommendations are of particular relevance to Europe:
  - Make the full range of DMTs available to people with active relapsing forms of MS, regardless of their treatment history, to speed up adoption of the most appropriate treatment strategy that optimizes effectiveness and safety for each individual.
  - Ensure that MS healthcare professionals can take the time to educate people with MS about strategies to manage their disease. Emphasize the importance of a 'brain-healthy' lifestyle (including actively screening for and managing comorbidities), the benefits of early treatment with a DMT, the likely consequences of inadequate or suboptimal treatment and the goal of minimizing disease activity while optimizing safety.

Long-term dissemination strategy

- The MS Brain Health initiative created a Steering Committee[2] to guide its ongoing strategy (**Figure 1**) for global dissemination and implementation of the report's recommendations.
- The report has so far been endorsed by 26 professional and patient organizations, including the European Committee for Treatment and Research in Multiple Sclerosis, European Brain Council, European Multiple Sclerosis Platform and Multiple Sclerosis International Federation.
  - The multidisciplinary nature of the author and working groups facilitated a number of these endorsements.
- MS Brain Health material aimed at patients and advocates has been proactively shared by endorsers and other individuals on social media.
  - The @MSBrainHealth Twitter account has gained over 1000 followers[9] and 245 000 tweet impressions.[10]
- MS Brain Health champions and endorsing organizations in more than 40 countries are positioned to share and publicize the report and its key recommendations at a local level.
  - Presentations to healthcare professionals have been given at nine meetings in five continents; many of these arose as a result of personal approaches from neurologists who are keen to speak about the recommendations and the brain health perspective on MS.
  - A slide deck for presentation to healthcare professionals is available,[11] and another for presentation to patients will be published soon.

Conclusions

- *Brain health: time matters in multiple sclerosis*, an international consensus report published in October 2015, was developed through structured discussions conducted by multidisciplinary author and working groups.
- The report presents an evidence-based position for a therapeutic strategy involving proactive monitoring and shared decision-making. Early diagnosis, improved treatment access and generating real-world evidence are also key.
- The policy recommendations are aimed at a range of stakeholders who can influence the quality of care.
- The multidisciplinary composition of the author and working groups has generated momentum for dissemination of the report to relevant audiences.
- The authors and Steering Committee warmly welcome proactive engagement by local stakeholders who desire to see change and who can build on this momentum.

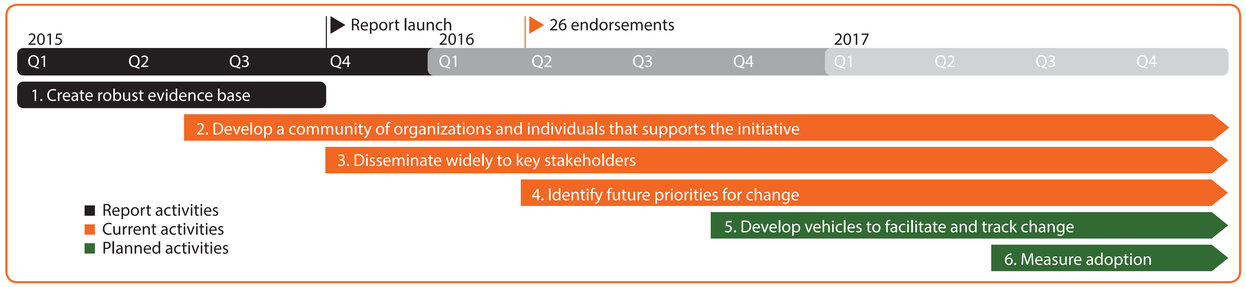

Figure 1. The six strategic steps shown are part of an overall plan to encourage the widespread adoption of the MS Brain Health approach and recommendations.

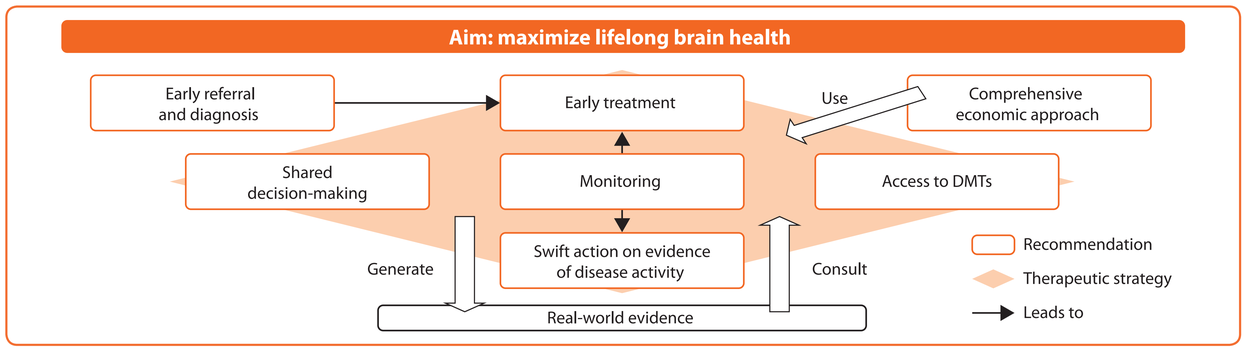

Figure 2. The report recommends a therapeutic strategy that aims to preserve central nervous system tissue and maximize lifelong neurological reserve (an important component of brain health) by reducing disease activity.

DMTs, disease-modifying therapies.

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

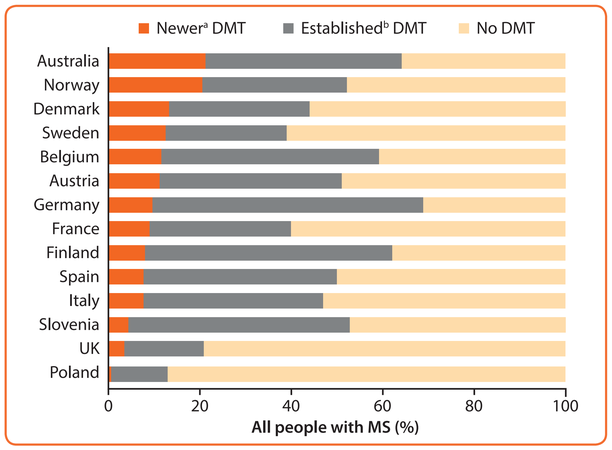

Figure 3. The proportion of people with all forms of MS receiving a newer DMT in 2013 varied considerably between European countries.

Data were generated from DMT sales figures as described in the original sources,[3,4] and therefore potentially include people with all forms of MS (relapsing or progressive) and do not differentiate between treatment initiation and treatment switching. All DMTs for Australia: calculation based on sales figures,[4] population[5] and number of people with MS.[6]
[a]Newer DMT is defined as a DMT approved for relapsing forms of MS that has a different mechanism of action from established DMTs.
[b]Established DMT is defined as a DMT approved for relapsing forms of MS during the 1990s or a reformulation or generic version of one of these agents.
DMT, disease-modifying therapy.

MS Brain Health
Time Matters

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Disclosures

G Giovannoni has received consulting fees from AbbVie, Bayer HealthCare, Biogen, Canbex Therapeutics, Five Prime Therapeutics, Genzyme-Sanofi, GlaxoSmithKline, GW Pharma, Merck, Merck Serono, Novartis, Oxford PharmaGenesis, Protein Discovery Laboratories, Roche, Synthon, Teva Neuroscience and UCB; and has received grant/research support from Bayer HealthCare, Biogen, Genzyme-Sanofi, Merck, Merck Serono and Novartis. H Butzkueven has received consulting fees from Biogen, Genzyme, Merck, Novartis, and Oxford PharmaGenesis; and has received grant/research support from Biogen, Genzyme, Merck and Novartis. K Costello has nothing to disclose. S Dhib-Jalbut has received consulting fees from Bayer, Genentech, Genzyme, Oxford PharmaGenesis, Serono and Teva; and has received grant/research support from Biogen and Teva Pharmaceuticals. J Hobart has received consulting fees, honoraria, support to attend meetings or research support from Acorda, Asubio, Bayer Schering, Biogen Idec, Genzyme, Merck Serono, Novartis, Teva, Oxford PharmaGenesis and F. Hoffmann-La Roche. G Kobelt has received consulting fees from 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 Biogen, Genzyme, Merck Serono, Oxford PharmaGenesis, Teva, Novartis, Roche and Vertex; and has received grant/research support from Biogen and Merck Serono. C Thalheim has acted as a speaker and adviser on non-product-specific subjects for Almirall, Bayer, Biogen, GSK, Novartis, Roche, Synthon and Teva; and has received consulting fees from Oxford PharmaGenesis. A Traboulsee has received consulting fees from Biogen, Genzyme, Roche, Oxford PharmaGenesis 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, Acorda, Biogen Idec, Consortium of MS Centers, DeltaQuest, Genentech, Novartis, Novartis Canada, Novartis Japan, Oxford PharmaGenesis, Roche, Teva and Teva Canada; and has received grant/research support from Biogen Idec, EMD Serono, Genzyme, NIH, Novartis, Ono, Roche, Rocky Mountain MS Center and Teva.

Preparation of the report and its recommendations was funded by an educational grant from F. Hoffmann-La Roche, who had no influence on the content.

MS Brain Health activities and supporting materials have been funded by grants from AbbVie, Actelion Pharmaceuticals and Sanofi Genzyme and by educational grants from Biogen, F. Hoffmann-La Roche, Merck Serono and Novartis, all of whom had no influence on the content.

Independent writing and editing assistance for the preparation of this poster and other MS Brain Health activities has been provided by Oxford PharmaGenesis, Oxford, UK, funded by the grants and educational grants from the organizations listed above.

Presented at the 2nd Congress of the European Academy of Neurology (EAN), 28–31 May 2016, Copenhagen, Denmark