



# EMSP

# Annual Congress 2012

Barcelona | 19th - 20th May



What you should know about MS and EMSP:

Multiple sclerosis (MS) is a complex, chronic, disabling disease, disrupting the transmission of signals in the brain. The average age of diagnosis is 20-40, a period when individuals are highly engaged in establishing their careers, raising their families and enjoying lifestyles. MS affects twice as many women as men. There are currently approximately 600,000 people diagnosed with MS in Europe each year. So far, no cure has been found.

The European Multiple Sclerosis Platform (EMSP) is the umbrella organisation for 38 MS societies from 34 European countries. EMSP represents their interests at the European level and works to achieve its goals of high quality equitable treatment and support for people with MS.

Its activities derive from a a mission comprising five main objectives:

- Encourage MS research **through recognised organisations**
- Exchange and disseminate information **relating to MS**
- Promote collaborative programmes **among national MS societies in Europe**
- Facilitate interaction **between institutions of the European Union, the Council of Europe and other organisations**
- Propose new measures **to advance the rights of people with MS and ensure their participation in society**

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# Opening Address to MS Conference

John C. Golding, EMSP President



*Volem agrair la presència avui amb nosaltres del  
Ecellentissim senyor Conseller de Benestar Social  
i Família de La Generalitat de Catalunya.*

For those of you that do not speak Catalan I have just said “First of all I would like to welcome the minister for Social Welfare and Family in The Generalitat of Catalonia”: Mr. Josep Lluís Cleris i Gonzàles.

I would also like to welcome all the speakers that will be addressing us during these three days and last but not least all the participants and guests taking part in this conference. That is to say CEOs and key staff volunteers of MS societies in Europe, representatives of MSIF, people with MS and their

caregivers, Young persons with MS, neurologists, representatives of RIMS, ECTRIMS, MS nurses, industry representatives and anyone else attending and interested in the issue of MS. It is my hope that those of you that are here for the first time took part in the Tour of Barcelona yesterday evening and savoured some of the stunning spectacles on offer in this beautiful city.

We have had a meeting of medical experts and the Annual Council meeting yesterday and we are now ready to move on by holding the Annual Conference and Youth Congress.

The EMSP is a platform for exchange of MS related information and examples of good practice. There are various channels for this task – our traditional Spring Conference is one of the most effective and important ones.

I would like to say a few words as to what you can expect to be addressed and discussed today and tomorrow.

As always in our Spring Conferences: A leading expert will present an update on new MS treatments in the pipeline (Prof. Alan Thompson).

We’ll learn about:

- The impact of female hormones on MS
- About the progress in re-myelination research
- About cannabis in management of MS symptoms and

In our workshops

- We will try to bring you closer to current EMSP projects and to a promising pilot project in Switzerland on MS and employment
- In parallel, the YPwMS will have their own discussions about sexuality and pregnancy.
- We’ll hear about national political developments in healthcare and social care since 2003, the year of the EU Parliament’s Resolution on MS
- And finally, we’ll try to inspire you by some examples of good practice in patient empowerment, taken both from national and from European level.

It is my sincere wish that you will find the programme interesting and rewarding and that it also allows you to socialise and renew old friendships and also make new friends and contacts at the same time.

I will now like to give the floor to Councillor Josep Lluís Cleris i Gonzàles from The Generalitat of Catalonia.

# Opening Session

Josep Lluís Cleries i Gonzàles, Minister of Social Welfare and Family, Generalitat of Catalunya



aim of highlighting the right for each person to be as able and independent as possible at any given moment in his or her life. Our intent is to recognise appropriately the value of each person’s capacity, and to be sure that each feels she or he is a protagonist – that is someone who advances positive action – within society.

To achieve this, governments have the responsibility to create an accessible society; this implies philosophies and practical action in areas such as universal access and eliminating barriers to employment, social activity and independent living. It also means looking at disease from a societal perspective, not just from the angle of health and healthcare costs.

To open this 2012 Annual Congress, I want first to congratulate the EMSP on its sterling work in the area of MS, which I believe has brought benefits to all the national MS Societies represented in this room and to the 600,000 people living with MS across Europe.

As you all know, Spain as a whole and its individual regions have had a long, hard struggle to achieve a welfare state. For many decades, the rights of people with disabilities received very little attention; they often lived in states of poor health, poor economic standing, and social isolation.

More recently, the government has put emphasis on defining disability and dependency, with the

Through the Ministry of Health and the Ministry of Social Welfare and Family, the Government of Catalunya is committed to early, effective and multi-disciplinary treatment for all people with MS. We aim to be patient-centred and believe that people with MS understand best what their needs are – and that we should listen to them and learn from them how to best meet those needs. Then we have a responsibility to coordinate our support so that these people who already have so many additional burdens because of MS do not have to waste their time and energy trying to make their way through a labyrinth of bureaucracy. It is our job to provide comprehensive services in an efficient manner.

Governments also need to take measures to break down the stigma that persists. In this regard, we often look for guidance from the MS societies who are close to the community and know the challenges. One activity I believe to be highly effective, which is organised each year by the **Federación Española para la Lucha contra la Esclerosis Múltiple (FELEM)** is known by the slogan **MULLA’T**. People who enjoy swimming – as do many people who have MS – seek sponsors who will contribute a sum of money for each kilometre they swim. The slogan of the campaign can be translated as in two ways: “take a dip” or “get engaged”.

It is my heartfelt wish that this message will spread throughout the able-bodied community, and that many more of people will engage in the effort to ensure that all people with MS receive dignified care throughout their lives, particularly as their condition evolves.

Given the current economic crisis in Spain, we are in a time when it is particularly difficult to move forward in advancing in these areas. But we see an event like this as an occasion to learn from others and, hopefully, to advance more quickly and at lower cost based on their experiences. With this in mind, I wish you a very successful and engaging Congress.





# Emerging Therapies and Multiple Sclerosis

Prof. Alan J. Thompson, University College London



Twenty years after the first effective medication for MS (Interferon-B) was approved by the US Food and Drug Administration, we can see encouraging milestones in the development of more therapeutic options. Just five years later, four agents were available that reduced relapse rates. Between 2004 and 2006, a second-line agent was licensed for more aggressive MS, withdrawn because of serious side effects and subsequently reintroduced. In 2010, we entered a new era of therapy, with the release of the first oral agent.

Yet the unmet needs are very challenging in terms of ensuring access to disease-modifying drugs world-wide and in developing strategies to suppress inflammation and to protect and repair the central nervous system. There is also great need in symptomatic treatment and in prevention of MS.

The pipeline of therapies under development reflects that research in MS therapies continues in three areas: regulating the immune system;

finding ways to keep leukocytes from crossing the blood-brain barrier; and protecting the CNS from demyelination or restoring the damage done to it. In the case of relapsing-remitting MS (RR-MS), one of the key areas is that of **monoclonal antibodies**, which target specific molecules.

The story of **Natalizumab** is well known: the therapy aims to seal the blood-brain barrier, making it impossible for leukocytes to enter the central nervous system (CNS) and attack tissue. In clinical trials against placebo over two years, Natalizumab showed an 81% reduction in the annual relapse rate and a 64% reduction in the risk of disability progression. But controversy arose from evidence that the treatment increased the risk of developing **progressive multifocal leukoencephalopathy** (PML). Further investigation saw the risk for PML increase from 1:1000 to 2.3:1000, but also provided better understanding of the risk factors involved, which include:

- the time period over which a PwMS is treated with Natalizumab;

- previous immune-suppression therapies; and
- the presence of virus (JCV) antibodies and the activation of the virus.

Importantly, methods have been developed to screen for JCV antibodies, making it possible to identify PwMS who are most at risk for PML. As treating neurologists, we can help patients make more informed decisions about risks, monitor the effects of treatment and make appropriate decisions as needed.

New monoclonal antibody therapies now either available or in Phase III clinical trials include **Alem-tuzumab, Ocrelizumab and Daclizumab**<sup>1</sup> all of which focus primarily on reducing the risk of attacks in RR-MS.

With patient quality of life in mind, much effort has gone into developing oral therapies as an alternative to those delivered by injection or infusion. At present, four agents are either available or in the process of becoming so: **Fingolimod, Fumaric Acid, Laquinimod and Teriflunomide**.

The greatest interest is on Fingolimod (marketed as Gilenya), which works by “sweeping up” the lymphocytes that attack the CNS. Two large clinical trials have shown positive results. In the TRANFORMS study, Fingolimod was tested against interferon b-1a; similar results were seen in the FREEDOMS trial, which compared Fingolimod with placebo. As a result of these trials, Fingolimod was approved for two groups:

- Patients with high disease activity despite treatment with a beta-interferon.
- Patients with ≥2 relapses in one year, and ≥1 Gd-enhancing lesion or a significant increase in T2 lesion load.

The studies revealed the need to monitor three areas of potential adverse effects: cardiovascular effects, a higher degree of respiratory infections and the development of malignancies (though no specific association has been verified).

**Fumaric acid** (Fumarate or BG00012) appears to dampen inflammation while also protecting against the neuronal death and damage to myelin

1| Those therapies shown in bold are currently in Phase III clinical trials.

## The unmet need is massive

Disease modification		
MRI, relapse reduction, delayed onset of CDMS, delayed disease progression, disease activity free, delayed onset of SPMS, prevention of SPMS		
Anti-inflammatory strategies	Neuroprotective strategies	Neurorestorative strategies
Symptomatic therapies		
Cognition	Fatigue	Spasticity
Bladder/Bowel	Mobility	Mood
MS prevention		
Vitamin D	Smoking	EBV







# Gender Differences in Multiple Sclerosis

Mar Tintoré, PhD, MS Centre of Catalonia (Cemcat), Neuroimmunological Unit, Vall d’Hebron University Hospital

The predominance of MS in women over men – a ratio of approximately 2:1 – is seen also in other auto-immune diseases. This suggests a relation between female reproductive hormones and autoimmunity. This gender link is further evidenced in the fact that in pre-adolescent MS the ratio tends to be 1:1 and in statistics showing that women in the relapsing-remitting stage tend to have a “more active” form of MS (characterised by more relapses). Although the causes are less clear, men appear more likely to advance to the secondary progressive stage or to be diagnosed with primary progressive MS.

Studies of women with MS before, during and after pregnancy further confirm this hormonal link. During pregnancy, Th1 cytokine levels decrease while Th2 cytokines increase. With half of the raw material of a foetus coming from the father, the mother’s body recognises the growing child as a “foreign invader”. To support its development, the mother’s body naturally suppresses the immune system mechanisms that might otherwise reject the invasion.

This immune suppression can have a protective effect for women with MS (Voskuhl and Gold, *Nat. Rev. Neurol.*, 2012).

The hormonal changes that accompany birth of a child are often seen to have the opposite effect: as levels of Th1 increase and Th2 fall down again, the risk of a post-natal relapse rises.

These findings are important for women with MS: they demonstrate that past beliefs (“pregnancy may be dangerous for the baby”, “a woman with MS cannot cope with a mother’s duties”, “your MS will worsen”, “your disease can be passed on to the baby”) about pregnancy and MS were not based on evidence. They also help to answer questions that all women with MS ask when considering whether to have a family.

**Will I have a normal baby?**  
**YES.** There is no evidence of MS having negative effects (such as malformations or infant death) on the health of offspring (Mueller et al., *Am J Obstet Gynecol*, 2002), nor are any changes noted for

age of walking or talking, or other developmental stages expected in the first year (Patti et al., *J Neurol*, 2008). There is no increased risk of low birth weight (Dahl et al., *Neurology*, 2005), except if the foetus is exposed to interferon B in the early stages of development (Boskovic et al., *Neurology*, 2005).

**Will my child have MS?**  
**The risk is slightly increased.** In the general population, the incidence of MS is about 0.2%. In cases where the mother or father is affected, the incidence rises to 3% to 5%. For dizygotic (fraternal) twins, the risk is quite low 3% to 5%; for monozygotic (identical) twins, the risk increases substantially to 20% to 26%.

**What if I get pregnant while I am on DMD treatment?**  
Most neurologists will advise women with MS to plan their pregnancies according to their own wishes, but taking into account the severity of their disease. All will recommend stopping treatment before trying to conceive. For DMDs, the treatment should be stopped approximately one month prior; for Natalizumab and

Fingolimod, it is recommended to discontinue three months in advance. The European Medicines Agency has four rankings for the risk level of all drugs during pregnancy; the main MS therapies are shown below:

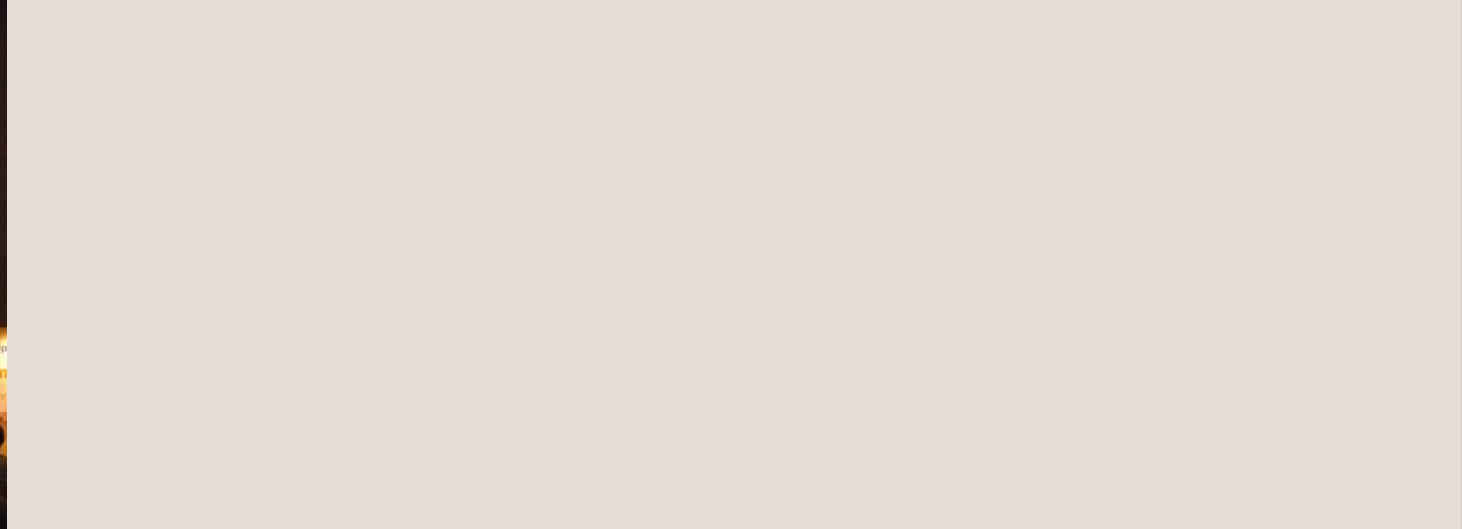
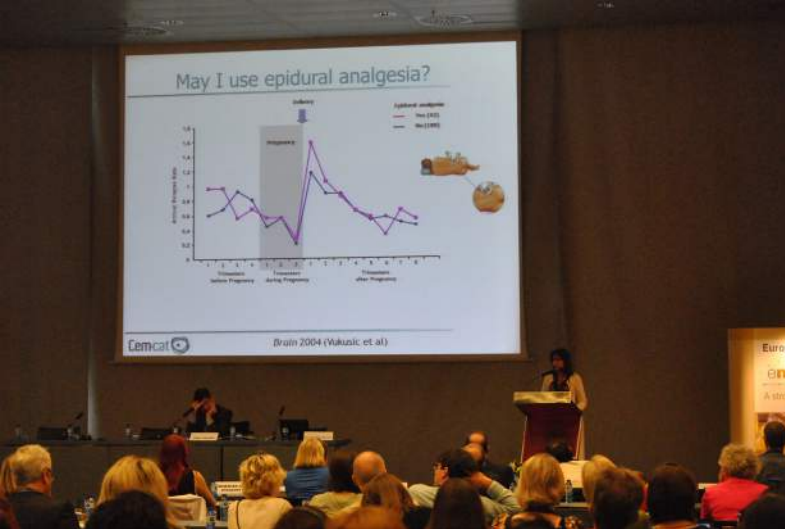
- **Category A:** No risk for the foetus.
- **Category B:** No risk for the foetus observed in animal studies. No controlled studies exist in pregnant women (**glatiramer acetate**).
- **Category C:** Animal studies have shown abnormalities in foetus. No controlled studies exist in pregnant women (**interferons, Mitoxantrone and Natalizumab**).
- **Category D:** Evidence of teratogenicity and abortions in studies or data during post-marketing.

But the fact remains – across the general population – that approximately 35% of pregnancies are unplanned. Thus in certain cases, the foetus could be exposed to the MS therapy during its earliest stages of development. A first study showed a small increased risk of spontaneous abortion, but no increase in the risk of congenital abnormalities (Boskovic et al., *Neurology*, 2005); however, other studies have suggested that the rate of pregnancy losses for women exposed to interferon beta matches

Table 1   Effect of sex-related differences and pregnancy on MS			
Patient characteristic	MS incidence (onset)	MS activity (relapse)	MS progression (disability)
Sex	Women more than men	Women more than men	Possibly men more than women*
Late pregnancy (third trimester)	Decrease	Decrease	None
Postpartum	Increase	Increase	None
Parity‡	No change (or possibly decreased) with increasing parity	Unknown	No change (or possibly decreased) with increasing parity
*Available evidence does not clearly demonstrate a sex-related difference with regard to disability or progression of disease. †No substantive evidence is available for the effects of parity. Abbreviation: MS, multiple sclerosis.			

## Sex-related factors in multiple sclerosis susceptibility and progression

Rhonda R. Voskuhl and Stefan M. Gold



that of the general population (Sandberg-Wollheim, *Neurology*, 2005). In another study of 88 Spanish women, covering both planned and unplanned pregnancies and reflecting exposure or non-exposure to DMDs, 75% of pregnancies advanced to full term while 25% were lost (V. De la Heras, et al., *Multiple Sclerosis*, 2007). For full-term pregnancies, no malformations or neonatal complications were reported (Fragoso et al., *CNS Drugs*, 2010) and the rate of Cesarean births matched the general population (Amato et al., *Neurol*, 2010).

One study shows some risk of increased relapse connected with the use of assisted reproduction techniques, but the findings need to be further investigated and confirmed (Hellwig et al., *European Neurology*, 2009). Similar findings were true for exposure to Glatiramer acetate (Salminen et al., *J Neurol*, 2010) and to Natalizumab (Hellwig et al., *MS Journal*, 2011), although the data for Natalizumab exposure are very preliminary.

**Will MS cause complications during pregnancy?**

**NO.** There is no evidence that MS increases complications during pregnancy in relation to the population at large (Mueller et al., *Am J Obstet Gynecol*, 2002).

**Will I have more relapses during pregnancy? Are relapses more severe during pregnancy?**

The PRIMS study group showed that relapse rates declined during pregnancy against the year prior to pregnancy; during the third trimester, the rate fell by as much as 70% (Confraveux et al., *N Engl J Med*, 1998; Vukusic et al., *Brain*, 2004). This appears to be related to lower levels of Th1 and increased levels of Th2. If a relapse occurs during pregnancy, physicians are better prepared to treat, selecting the appropriate therapy (typically with methyl prednisolone) in relation to the severity of the attack.

**Will I develop new symptoms during pregnancy?**

**POSSIBLY.** Some women experience an aggravation existing symptoms or notice new symptoms, particularly in the areas of urinary problems, fatigue, sensory symptoms and gait abnormalities.

**Will MS cause complications during delivery?**

**NO.** There is no evidence of increased complications during delivery (Mia van der Kop et al., *Ann Neurol*, 2011; Mueller et al., *Am J Obstet Gynecol*, 2002).

**Can I have an epidural during delivery?**

**YES.** Available data do not show any increased risk of relapse in response to epidural (Vukusic et al., *Brain*, 2004).

**Can I breastfeed?**

**YES.** There is no evidence that breastfeeding increases the rate of relapse or disability (The PRIMS study group, *N Engl J Med*, 1998). One small study suggested that breastfeeding may have a protective role against relapses (Langer-Gould et al., *Arch Neur*, 2009), but this was not confirmed

in a larger follow-up study (Airas et al., *Neurology*, 2010). The decision to breastfeed appears to be associated with a milder disease activity; the relapse rate among women breastfeeding (~50%) was much lower than for those not breastfeeding (>80%) (Portaccio et al., *Neurology* 2011)

**Will I have more relapses after my child is born?**

**POSSIBLY.** Following delivery, the situation that seems to protect a pregnant woman is reversed: Th1 increases and Th2 decreases, which correlates with increased risk of relapse. Today, physicians are better able to predict who is at risk of post-partum relapse, which appears to be linked to three factors: a) the number of relapses in previous years; b) the number of relapses during pregnancy; and c) the degree of disability at the onset of pregnancy (Vukusic et al., *Brain*, 2004).

If an attack occurs post-partum or during breastfeeding, the decision to treat or not should be taken together with the doctor. If treatment is to be pursued, the patient should stop breastfeeding.

Trials are ongoing to assess the possibility of preventing post-partum attacks through the use of steroids, (intravenous immunoglobulin (IVIg), estrogens or DMDs.

**Will my MS worsen following delivery of my child?**

**NO.** Studies indicate that deterioration post-partum and two years following is not beyond what is expected in the course of MS in relation to the type and stage at which the pregnancy occurs (Vukusic et al., *Brain*, 2004).

**How soon should I restart treatment?**

**IT DEPENDS.** Generally, restarting treatment is related to the severity of MS. It is important to note that women who restart treatment must discontinue breastfeeding.





## Progress in remyelination research

*Catherine Lubetzki, Prof. of Neurology, Hôpital Pitié-Salpêtrière, France*

Myelin is a white membrane (80% lipid and 20% protein) that forms an insulating sheath (**myelin sheath**) around nerve fibres. It is crucial to the protection of axons in the central nervous system (CNS) and necessary to the rapid transmission of electrical impulses from one nerve to another. When demyelination occurs, the “slot” of missing myelin causes the nerve to miss-fire – or not to fire at all. In MS, the loss of messaging between axons leads to clinical symptoms and the loss of axons (due to the loss of the myelin protection,) leads to increased disability. The symptoms depend on the location of the demyelination.

### Remyelination studies

Historically, it was believed that damage to the myelin sheath could not be repaired. Over the past 50 years, research has confirmed that remyelination does occur naturally, which ultimately prompted investigation into how it can be stimulated.

In 1961 Bunge and others reported the first evidence that remyelination occurs spontaneously, along with recovery of the impulses that had been lost. This was seen in the spinal cord of an adult cat.

In 1965 Perier and Gregoire found evidence of the first remyelination in patients with MS. In 1981 K.J. Smith and W.I. McDonald found that remyelination could restore rapid conduction of electrical impulses.

From 2000-2008 – The groups of B. Blake-more (in experimental models) and of H. Lass-mann (in MS tissue) confirmed that myelin protects axons from degeneration. Therefore, re-myelination leads to protection against disability.

### How does remyelination occur?

Once the possibility of remyelination was confirmed, the logical question was to ask: *How does it occur?* Further research shows that three types of cells are involved, each acting in different areas of the body. Each shows different potential to promote remyelination, in terms of both rate and zone.

**Progenitor cells** are a sub-set of cells that are not fully formed and, like stem cells, have the ability to differentiate into diverse adult cells. The most important difference is that stem cells can replicate

indefinitely, whereas progenitor cells can divide only a limited number of times. Progenitor cells are found in the sub-ventricular region of the brain and can definitely contribute to remyelination, but within a very limited region of the brain.

**Oligodendrocytes precursor cells** are immature cells that persist in the adult CNS. They were ignored for many years because there was no marker to identify them. Today, we know that **oligodendrocyte precursor cells** account for 5% to 8% of all adult CNS cells, and that they are found throughout the CNS, both in the brain and in the spinal cord. After demyelination, they are attracted to the damaged area of the brain or spinal cord: once they establish contact with the nerve fibre, they can develop into oligodendrocytes, which are the cells that make up the myelin sheath. **Oligodendrocytes precursor cells are now considered as the main contributors to remyelination in the adult CNS.**

**Schwann cells** are a type of glial cell that form the myelin sheath in the peripheral nervous system (PNS). There is evidence that Schwann cells might contribute

to remyelination in the spinal cord, but not in other areas of the CNS.

### Why does remyelination fail in MS?

Seeing that this possibility for remyelination exists, we want to understand why it fails in MS. For this, we must first understand the different steps of the remyelination process. At present, all of this knowledge derives from experimental studies, both *in vivo* and *in vitro*. The main steps of the repair process are: recruitment of **oligodendrocyte precursor cells** to the demyelinated plaque; maturation into oligodendrocytes; and wrapping new myelin sheaths along the denuded axons. In general, two main approaches for therapy have arisen from recent research: 1) finding ways to inhibit activity that blocks naturally occurring remyelination; and 2) transplanting cells (stem cells) that can develop into myelin cells in the area surrounding the lesion.

**Inhibitors:** various research groups are trying to develop compounds that promote remyelination. One of the most interesting and advanced is associated with Lingo-1, a natural protein in the brain and spinal cord that inhibits oligodendrocyte maturation and







therefore prevents remyelination. Researchers are trying to develop compounds that inhibit production of Lingo-1. Some of these have been shown to be effective in experimental models. Phase 2 trials will begin soon, but it will be some time before this therapy is proven and available to patients.

**Transplantation:** efforts to transplant stem cells have been tried using cells from bone marrow, from the peripheral nervous system, and from other sources. Five aspects of this line of research are of note:

- Hematopoietic stem cells (HSC) therapy leads to profound immunosuppression, but makes no contribution to repair (remyelination).
- Therapy using stromal cells also acts by modulating the immune system, however without demonstrated repair function
- Schwann cells can be transplanted to stimulate remyelination, but they do not migrate within the CNS, so their effect is limited in regional scope.
- Neural stem cells also have an immune-modulatory role and might participate to repair indirectly

(bystander effect) by favouring endogenous remyelination. However, their accessibility might be a concern.

- Stem cells from other sources:
  - Olfactory ensheathing cells (OECs) are found in the lining of the nose. Although they do not form myelin in normal conditions, when transplanted to the area of a demyelinated lesion, they are able to remyelinate.
  - Boundary cap (BC) cells are located at the interface between the central and peripheral nervous systems during development. Early studies show that BC cells are highly mobile and have a strong potential for stimulating remyelination.

#### At which stage of MS is remyelination effective?

As demyelination is an ongoing process in MS, it is valid to examine when treatment aimed at remyelination would be most effective: This is still an open question. In concluding, I wish to say a few words about the need to have hope as research advances in various areas of MS

therapy – and yet be cognisant of the need for scientific proof that therapies are effective. Even if we are some years away from having a therapy to offer from the current work in endogenous remyelination, recent progress targeting inhibitors of remyelination is very encouraging.

The same is true of stem cell therapy, which is still in quite early stages of investigation. It is important for people with MS to understand that much more academic investigation is needed in this area. Stem cell clinics are currently selling something other than effective treatment: they are offering only hope and illusion. They say that they cure everything, but they are doing it for money, not for science.





# Cannabis in the Management of MS Symptoms

Patrick Vermersch, University of Lille Nord de France

Spasticity, like all MS symptoms, occurs as a result of myelin and nerve fibre degradation. It ranks seventh of the top 10 symptoms of MS: 82% of patients report experiencing spasticity, among which 54% say the symptom is moderate to severe. It is one of the most disabling symptoms, and one of the greatest unmet needs in symptomatic treatment. At present, spasticity progresses despite available treatment to reduce its impacts, and many patients judge the current treatments as unsatisfactory.

The Ashworth Scale is the most common tool that physicians use to measure the degree of spasticity, but it has limitations in terms of sensitivity, reliability and validity. The Numerical Rating Scale offers an alternative and more reliable method in which patients rate their own symptoms (on a scale of 1-10) for each 24-hour period.

Recently, there has been increased interest in the use of cannabinoids to treat spasticity in MS. Cannabis (*Cannabis sativa*) has a long history of

use as both a medicine and a recreational drug. Medicinally, **street cannabis** has been used for its anti-spastic, muscle relaxant and pain relief effects. In a UK survey of persons using cannabis medicinally (mostly smokers) between 1998 and 2002, almost 75% indicated that it was better or somewhat better than their previous treatment for MS or various pain states (Ware et al. *Int J Clin Pract* 2005;59: 291-95).

Apart from the associated legal issues, use of street cannabis raises other concerns. It lacks standardisation and purity and recent samples reported high levels of tetrahydrocannabinol (THC; the psychoactive cannabinoid) and low levels of cannabidiol (CBD; the anti-psychotic cannabinoid). Moreover, it is also known that smoking cannabis increases the risk of lung cancer, heart disease, etc., and that the substance has variable pharmacokinetics that cause very high THC peaks, which lead to psychoactivity and other adverse events (Chong et al. *Mult Scler* 2006; 12: 646-51; Wade et al. *Mult Scler* 2006; q12: 639-45; Aldington et al. *Eur Resp J*

## Ashworth scale is the most commonly used scale to measure spasticity

Score	Modified Ashworth Scale
0	No increase in muscle tone
1	Slight increase in muscle tone, manifested by a catch and release or by minimal resistance at the end of the range of motion when the affected part(s) is moved in flexion or extension
1+	Slight increase in muscle tone, manifested by a catch, followed by minimal resistance throughout the remainder (less than half) of the range of movement (ROM)
2	More marked increase in muscle tone through most of the ROM, but affected part(s) easily moved
3	Considerable increase in muscle tone, passive movement difficult
4	Affected part(s) rigid in flexion or extension

- Limitations: lack of sensitivity, reliability and validity

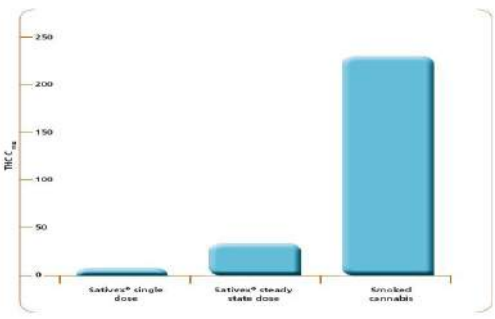
2008; 31: 280-86.; Potter et al. *J Forensic Sci* 2008; 53: 90-4).

These concerns prompted the development of cannabis-based pharmaceuticals. A key aim was to produce a standardised medicinal product based upon the main active constituents of *Cannabis sativa*: tetrahydrocannabinol (THC) and cannabidiol (CBD). Under controlled conditions, the substance can be formulated to ensure purity and stability. As an alternative to smoking, the therapy was developed to be administered through an oral/nasal spray (oromucosal) that provides a satisfactory pharmacokinetic effect while avoiding the high plasma levels and risks associated with smoking. This approach allows the benefit of the synergistic interaction between CBD and THC, with reduced psycho-activity and enhanced cannabinoid-mediated clinical effects. Looking particularly at the drug Sativex, it is prepared from two cloned chemovars of *C. sativa* to ensure standardisation and quality. One clone produces high levels of 9-delta-tetrahydrocannabinol (THC) and the other

high levels of cannabidiol (CBD). These two cannabinoids account for about 70% of the composition of Sativex; the remaining 30% comprises minor cannabinoids, terpenoids, sterols and triglycerides.

Endocannabinoids are “Retrograde” Neuromodulators – i.e. they are released from post-synaptic neurons and act at cannabinoid CB<sub>1</sub> receptors on pre-synaptic axon terminals. THC links to both CB<sub>1</sub> and CB<sub>2</sub> receptors, showing greater activity at CB<sub>1</sub> subtypes (which may account for its psychoactivity). CBD has lower affinity for both receptors and is an antagonist at the CB<sub>1</sub> receptor. Thus, CBD may act synergistically with THC to antagonise psychoactive and sedative effects while enhancing cannabinoid-mediated clinical effects. The two active ingredients, which are absorbed and appear in the plasma within 15 minutes, have complementary effects: (see table).

## Maximum plasma THC levels with Sativex and Street Cannabis (smoked)



THC	CBD
Antiemetic	Analgesic
Analgesic	Anti-convulsant
Muscle relaxant	Anti-psychotic
Appetite stimulant	Anxiolytic
Psychoactive	Neuroprotective
Russo & Guy <i>Med Hypotheses</i> 2006; 66: 234-46.	



Sativex third pivotal clinical trial:  
two-phase study design



Patients experience somewhat different degrees of effect, which highlights the importance of tailoring dose amounts. The cannabinoids are quickly absorbed into body fat, but plasma concentrations following oral/nasal spraying are lower than those after inhalation because absorption is slower and redistribution into fat is rapid. The falling off of the effect happens in two phases; the initial effect falls off within about four hours and the substance is fully metabolised (by the liver) within 24 to 36 hours.

The first clinical trial of Sativex, carried out in the United Kingdom and Romania, included 189 patients and assessed (as the primary outcome) the change in severity of spasticity using the Numerical Rating Scale. Secondary outcomes included the Ashworth scale, the motricity index, daily mean spasm scores and the patient’s global impression of change (Collin C et al. *Eur J Neurol* 2007; 14: 290-96). NRS scores were shown to be reduced by about 50%, with patients reporting an improvement of  $\geq 30\%$  (from a baseline).

A second, wider clinical trial had 337 participants across Europe and included additional secondary outcome measures such as the timed 10-m walk, the Berthel ADL index, the Carer’s global impression of change, quality of life, and safety and tolerability. Again using the NRS, patients improved by  $\geq 30\%$  (from baseline) and also scored improvements on other symptoms: fatigue (51%); spasm (76%); bladder (73%); tremor (80%); pain (76%) and sleep (61%).

A third trial expanded to include 572 patients in a two-phase study, with results again showing a  $\geq 30\%$  improvement. The measures of quality of life improvement were significant in this study: higher scores on the Berthel scale of activities of daily living; patients, carers and physicians noted higher global impressions of change; less sleep disruption; lower spasm frequency; and higher quality of life scores (Ambler et al. *Mult Scler* 2009; 15: S258; Montalbán & Wright *Mult Scler* 2009; 15: S272).

A subsequent long-term, follow-up study assessed patients who remained in the study for at least one year: symptom scores remained significantly lower with Sativex than baseline values. For example: spasticity was scored at 69.5 (0 weeks), 34.2 (10 weeks) and 31.8 (82 weeks). Of 25 patients who interrupted treatment for two weeks, 20% needed to resume Sativex before the end of 14 days due to re-emergence of marked symptoms. During the interruption period, seven patients reported that their MS symptoms were much worse, 10 said that they were worse, 5 the same and 3 reported an improvement in symptoms.

It is important to examine the adverse effects (AEs) of Sativex. During the first four weeks of exposure, the most common effects were dizziness (14% to 32%) and fatigue (12% to 25%); both were usually reported as mild to moderate and resolved quickly. When the recommended gradual “up titration” schedule was introduced, the incidence of AEs declined. Overall, the rate of withdrawal from the trials due to AEs was

low. Importantly, Sativex does not exhibit the side effects typically associated with recreational cannabis use (Wade et al. *Mult Scler* 2004; 10: 434-41; Wade et al. *Mult Scler* 2006; 12: 639-45; Collin et al. *Eur J Neurol* 2007; 14:290-96 ; Collin et al. *Mult Scler* 2007; 13: S129; Ambler et al. *Mult Scler* 2009; 15: S258).

There is no evidence from these randomised clinical trials (RCTs) that Sativex poses any long-term or irreversible neuropsychiatric or cognitive risk to patients. The potential for abuse of Sativex is quite low, in part because the drug does not exhibit the psychostimulant effects typically associated with recreational cannabis use. Any sense of intoxication was reported to be very low during the course of short- and long-term studies. Sativex has not been associated with signs of drug tolerance and in a long-term trial the mean dosage decreased slightly. Finally, no consistent withdrawal syndrome has been observed, and there is no evidence of drug misuse or abuse.

Results from controlled RCTs provide conclusive evidence of the short- and long-term efficacy of Sativex in MS-related spasticity, with half of patients clearly receiving benefit from this add-on treatment.



# Threats to Adequate MS Treatment in Portugal

Jorge Da Silva, CEO, MS Society of Portugal

Before mid-2011, health care was almost free for everyone in Portugal, with costs being covered by the National Health Service (NHS) network. Hospitals and health centres provided services for people seeking treatment, regardless of their income or the health situation.

Due to the economic crisis, the newly elected government took strong steps towards making drastic cuts in state expenditure in all areas. This has affected the health budget and, accordingly, the treatment of PwMS.

The NHS is has been given targets to reduce the share of health budget within gross national product (GNP) by 1.25% in 2012 and a further 1% in 2013. Over the period 2010-13, this equates to a 40% reduction in costs within the NHS itself. In 2012 alone, the health budget has been cut by EUR 800 million. Cuts are already evident on street pharmacy profit margins (many pharmacies are closing) and in the fact that guidelines and central purchasing plans for hospital products (including oncology, AIDS and MS) are targeting

a 15% savings. Six months after the reforms were announced, 39 guidelines have been issued (with a target for 50 before the end of the year) and the pharmaceutical market in Portugal has been forced to reduce retail prices by 20% (compared to Aug 2011) (IMS Health).

In 2012, the average street pharmacy will show a negativeprofitof -€39,891 andanegativeoperating income of -€739. Expenditure on staff will represent 17.2% of sales value and 57% of total costs. It is expected that about 1,200 pharmacies will close in 2012, with a net loss at all levels.

In recent years, treatment of MS in Portugal has been state of the art. Of an estimated 5,000 PwMS, more than 3,500 were actively being treated. Once early symptoms were identified by a general practioner, patients were quickly referred to ophthalmologists or neurologists, or to other members of a network of highly skilled MS specialists. MS nurses have played a very important role in education, training and managing patients.

# MS Treatment – State of the Art



- **Patient Associations**  
SPEM – Sociedade Portuguesa de Esclerose Múltipla  
ANEM – Associação Nacional de Esclerose Múltipla  
TEM – Todos com a Esclerose Multipla
- **Medical Society**  
GEEM – Grupo de Estudos de Esclerose Múltipla
- **Treatment Centers**  
34 in 42 hospitals have MS Department  
**4 main hospitals:**
  - S. João – Oporto
  - CHUC – Coimbra
  - Sta. Maria – Lisbon
  - Hosp. Capuchos – Lisbon
- **Medications available** (100% reimbursed)  
Interf Beta 1a – Avonex / Rebif  
Interf Beta 1 b – Extavia / Betaferon  
Copaxone  
Tysabri  
Gylenia
- **MS Consensus** under development
- **National Commission** was created to validate MS Centers and patient treatment (current and newly-diagnosed patients)
- **Increased pressure on HCP** to reduce or minimize treatment costs.
- **Increase co-payment** for medical assistance
- **Reduce access to treatment** (MRI, patient transportation)

Since the reforms, the MS Society has noted some substantial changes, even though the fundamental mechanism of prices being settled by the Minister of Economy and Regulatory Authorities remains unchanged.

Before	Today
<ul style="list-style-type: none"><li>• SPMS (National Purchase) set tenders based on price and/or national guidelines</li><li>• MS specialist prescribed treatment based on patient needs / patients had free access to treatment and prescriptions</li><li>• Hospitals purchased medication from pharma companies based on SPMS catalog and supplied patients through hospital pharmacies</li></ul>	<ul style="list-style-type: none"><li>• SPMS (National Purchase) set tenders based only on price; national guidelines have been eliminated</li><li>• Hospitals are creating sub-groups to select products based only on price and own clinical criteria; these clinical criteria could be different from region to region</li><li>• Only two products (one 1<sup>st</sup>-line; one 2<sup>nd</sup>-line) will be available for patients</li><li>• No more free prescriptions</li><li>• If the prescription is different from what hospital provides according to administration guidelines, it will have to be approved by the pharmacy commission</li><li>• Difficulties in accessing treatment are increasing. For example, access to MRI is reduced, which increases difficulties in obtaining a diagnosis. Hospital pharmacies are delivering DMDs for only one week of treatment, instead of the usual one month.</li></ul>

The guideline that hospital pharmacies should deliver only one week (rather than one month) of DMD therapy aims, in part, to avoid the loss of drugs that occurs when patients abandon the treatment. Under the new guideline, only 1 week is lost in such cases. But the guideline is very disadvantageous for people who live far away from hospitals: the time and cost associated with the weekly trip fall to the patient’s family, not on the government’s budget. Several fundamental problems are evident in the new model. With no national guidelines in place, decision making takes place locally and is inconsistent, often based only on price considerations. Difficulties in accessing MRI have a negative impact on diagnosis. Limitations on therapeutic options have effectively transferred the important role of the physican making the best decision for each patient to the hospital’s administrative authorities: neither physician decisions nor patient needs are adquately respected. Ultimately, reduced access to treat-ment increases the risk of more rapid disease progression for patients.





# Empowerment Case for Poland

Luiza Wieczyńska, Deputy CEO, MS Society of Poland (PSTR)



Since EMSP launched the MS Barometer in 2008, Poland has consistently been placed among the lowest-ranking countries in Europe. In 2011, Poland achieved a score of just 87 points out of a possible 225 – precisely 140 points below the first-placed Germany. But such comparisons are only one aspect of the MS Barometer; the other benefit of the tool is that it facilitates measurement of year-to-year progress within a given country. Unfortunately, even on this scale Poland has seen very little change: in 2009, Poland scored 79.

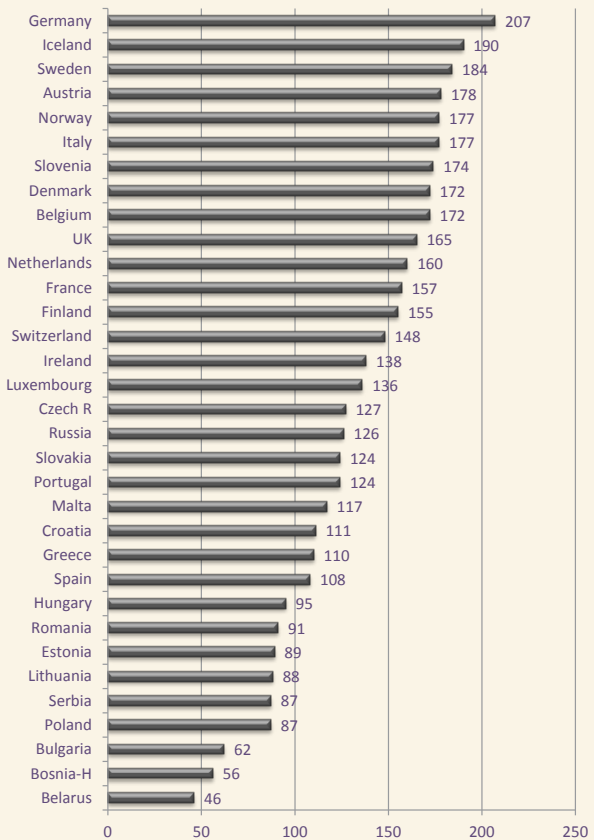
Access to the latest MS therapies is among the areas in which Poland attains a low score (22/70), placed sixth from the bottom). But somewhat surprisingly, Poland ranks 14<sup>th</sup> from the top in terms of empowerment of PwMS and has seen substantial progress in the past two years – rising from a score of 8 in 2009 (of a possible 35) to 18 in 2011. The key achievement is that PwMS are now represented in the MS Parliamentary Group. This consultation group comprises 13 Members of Parliament from diverse political backgrounds but united by a common interest: improving

the situation of PwMS. Since it was established 2011, the Group has met six times (organised by the PSTR) and has written numerous letters and undertaken various interpellations such as supporting PTSR initiative to change the rules restricting the therapy access.

Intense lobbying efforts of the PSTR, including the hosting with EMSP (in 2011) of a High-Level Roundtable, have also been empowering for the Society and for PwMS. Last year, the limitation on access to DMDs was extended from 3 years to 5 years, and an age restriction for those over 50 was eliminated. These advances still fall short of reflecting the recommendation of the *European Code of Good Practice in MS*, which states that treatment should be continued as long as benefit is evident. Such hard-won progress in the right direction is cause for celebration, but one must not overlook the reality that each PwMS in Poland has to face not only the disease, but a restrictive policy environment. For this reason, the Medical Advisory Board of the PSTR undertook (in 2005) to develop a National

Therapy Plan (NTP), which closely follows the Code of Good Practice in terms of content and includes a detailed budget (updated annually). The Plan is multidisciplinary and emphasises the importance of multiple tasks in the course of treatment: disease-modifying therapy, rehabilitation, symptomatic treatment, the establishment of a national registry, etc. It aims to provide a comprehensive and professional system of care for PwMS. In 2012, the PSTR will update the content of Plan to reflect new treatments that have become available.

The Plan aims to see 500 new PwMS gaining access to DMDs each year, and to ensure that all those being treated receive an MRI annually to assess disease progression. Importantly, the Plan also calls for the opportunity for PwMS to change drugs during treatment if they find that one is not as effective as hoped or causes intolerable side-effects. Finally, the Plan calls for workshops and trainings for neurologists, nurses, rehabilitation experts and other MS specialists.





## A “Starting Point” for Living with MS

*Kent Andersson, Treasurer of Neurologiskt Handikappades Riksförbund (NHR), the Swedish Association of Neurologically Disabled*

**avstamp**, the name selected for an educational programme for newly diagnosed PwMS, carries a strong sense of forward momentum: it translates as “starting point”, “kick-off” or “take-off”. The programme was launched by the Swedish Association for Persons with Neurological Disabilities (NHR) in response to a survey (2004) showing that many PwMS felt poorly informed following their diagnosis.

The **avstamp** programme aims to provide accurate information and give PwMS an opportunity to meet informally with experts and others who are newly diagnosed. NHR works closely with the Neurology Clinic, particularly MS nurses who play the critical role of identifying and inviting PwMS to attend **avstamp** events. Normally, participation is limited to about 12 people to provide a comfortable degree of intimacy.

The programme is delivered over four evening sessions, covering four aspects of living with MS with relevant experts giving presentations and

leading the discussion:

- What is happening in mybody?  
Lecturers: Neurologist + MS Nurse
- Psychological aspects and society’s responsibility  
Lecturer: Psychologist + Welfare Officer
- Living with MS in daily life  
Lecturer: Physical Therapist + Occupational Therapist
- 4th evening: A separate lecture for family and friends

The final evening is an important opportunity to explore how MS affects family life. NHR finds that most PwMS bring at least three family members to this evening, confirming that the disease touches everyone.

NHR feels programmes like **avstamp** should be a priority: many newly diagnosed patients feel that early treatment focuses solely on getting access to the right drugs. **avstamp** provides an opportunity to explore other topics important to coping with the reality that one has a life-changing disease.

**avstamp** is offered regularly in 15 centres across Sweden. However, NHR recognises that not

everyone can attend in person. Thus, in 2012, the Association will launch an online version of the programme that anyone can access. The site specifically encourages those who visit to establish personal contact with other PwMS to share learning and experiences.

NHR was established in 1957 as an MS Society. Today, it represents a broader range of neurological disabilities and has approximately 13,000 members, of which 60% have MS. NHR offers services through 96 local branches throughout Sweden.



### avstamp: Project history

In a 2004 survey, 149 members were asked how their need for information was fulfilled:

- 59% were not satisfied with the information given from the clinics when they were newly diagnosed
- 72% claimed to be left on their own collecting information after getting their diagnosis
- NHR was often said to be the most important information provider

## National political developments in health and social care since 2003 in Serbia

*Irena Dujmović Bašuroski, MD, PhD, Ass. Prof., Neurology, University of Belgrade*



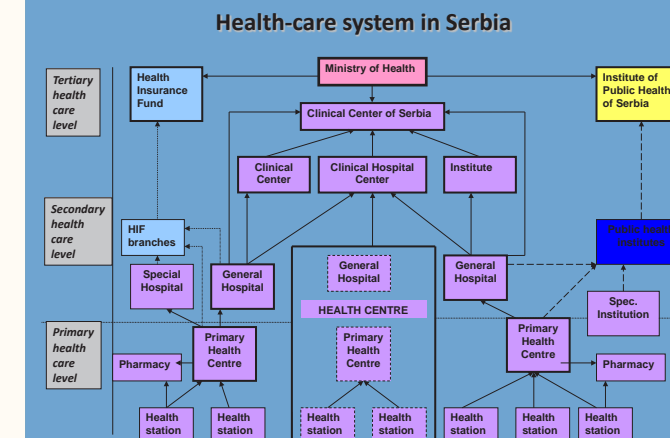
Serbia (excluding Kosovo) has population of 7.1 million people, which is declining as the death rate (13.85/1,000 people) exceeds the birth rate (9.19/1,000) and the fertility rate for women is 1.4. The median age is currently 41.3 years; average life expectancy is 71.49 for men and 77.34 for women. Health expenditure accounts for 9.9% of GDP and the physician ratio is 2.035/1,000 population.

The national health system offers three levels of care – primary, secondary and tertiary – and operates on a principle of universal access, with all costs being covered by the national health institution. However, to obtain care, an individual must obtain a health card, which requires registration of the place of residence. A key challenge in this regard is that a very low portion of the Roma population is registered and many do not have legal status. It should be noted, however, that in cases of emergency, health services are provided to all in need. In 2001, the Serbian healthcare system was functioning poorly on several levels. Overall, the

system was very fragmented, which had a negative influence on the continuity of care. Services were marred by low efficiency and uneven quality, and by a lack of motivation to engage in health promotion and disease prevention. Attempts to include health consumers in primary health care (PHC) policy decisions were taken with a non-systematic approach and therefore of limited value.

In 2002, the government launched a reform of the healthcare system based on a report entitled **Health Care Policy: The Vision of Health Care System Development**. A 2006 analysis noted the development of a network of PHC institutions (comprising 158 PHC centres) and stated that 36% of all doctors work in PHC, with general practitioners making up 17% of the total number of doctors.

The reform has achieved several important aims, including a better definition of healthcare institutions according to the healthcare levels. At the individual level, the chosen doctor concept





Health-related strategies of the Republic of Serbia

- Poverty reduction strategy paper (2003)
  - Action plan for children (2004)
  - Action plan for health of Roma population (2005)
  - Strategy for elder population (2005)
  - National Strategy for Fight Against HIV/AIDS (2005)
  - Strategy for Youth Development and Health in the Republic of Serbia (2006)
  - Tobacco Control Strategy (2007)
  - Strategy for the Development of Mental Health Care (2007)
  - Strategy on Occupational Safety and Health (2009)
- Program for Protection of the Population from Communicable Diseases 2002 -2010 (2002)
- Program for Protection of the Population from Tuberculosis (2005)
- The Strategy for Continuous Improvement of the Quality of Health Care and Patients’ Safety, The Strategy for Prevention and Control of Non-communicable Diseases, The Strategy for Palliative Care, The Strategy for the Fight against Drugs..



was introduced, which also facilitated the separation of the specialist-consultant service. Local communities became more vested in the ownership of the PHC centres and management of PHC institutions was largely decentralised. Importantly, preventative centres were developed through a **European Agency for Reconstruction** project for Improving Preventive Health Services in Serbia. Serbia also received funding from the Canadian International Development Agency (CIDA) to support the PHC system development (Balkans Primary Health Care Policy Project).

Building on these achievements, Serbia is now focused on the implementation of a Strategy and Action Plan of the Health Care System Reform until 2015, which is based on numerous documents published in the past 10 years, as well as on legislation enacted at national and local levels.

The reforms aim to improve health care for all, starting with a clear vision and advancing to a strategy and action plan *The 2010 Serbia*

*Progress Report*, prepared by the European Commission noted progress in many areas, but also identified those in which plans had not been implemented. In response, the Serbian government has prepared a new strategic document, *Serbia 2020*, which sets out two main goals:

- To define the framework for the Republic’s socio-economic development up to 2020.
- To continue reforms in the sphere of health care, both in terms of finance and management of the system, with the strategic goal of improving the quality of health of all citizens, especially children and vulnerable groups.

Serbia acknowledges the high value of cooperation with NGOs and aid organisations in working toward these goals.

Complementary to the health care reform, Serbia has also made substantial progress in five areas of social care: developing a strategy for social care; introducing new social welfare law and sub-laws; establishing a social protection chamber; deinstitutionalising children with disabilities; and

promoting cross-sectoral cooperation, including intersectoral committees for additional support for children with disabilities (social care, health and education).

A strategy plan launched in 2005 focused on establishing a network of community-based social care services (instead of social care institutions). It also sought to transform residential social institutions and decentralise social care services and institutions. This effort was based on 130 local social care strategies; by 2008, Serbia had achieved a re-organisation of centres for social protection, including the implementation of new standards and regulations.

The Social Welfare Law adopted in Parliament on 31 March 2011 (applied since 12 April 2011) represents the largest shift and most “pro-poor” and “pro-inclusion” legislative change the welfare system has introduced over the last decade. It legitimises the strategies developed since 2000 (e.g. Poverty Reduction Strategy and Strategy for Development of Social Protection) and mainstreams many donor and pilot reform initiatives implemented. The new

law is complemented by several sub-laws, such as the sub-law on community service standards, which was developed through consultations with social protection stakeholders and is aimed to be adopted by the end of 2012.

The social protection chamber establishes ethical regulations and oversees licensing for social care professionals.

In undertaking health and social reform in parallel, and establishing clear priorities in both areas, Serbia has taken an important step towards a more holistic approach to the overall well-being of its citizens – particularly those in vulnerable groups. Historically, the poor and disabled in Serbia have faced discrimination and unemployment, and experienced limited access to education and financial assistance.

It goes without saying that people with MS fit into this group of vulnerable persons. The MS Centre at the Clinic of Neurology, Clinical Centre of Serbia (Belgrade) estimates that there are 6,000 PwMS in the country. The main problem is limited

Legal basis for system development and health care reform

System laws:

- Health Care Law (2005)
- Health Insurance Law (2005)
- Medical Chambers Law (2005)
- Law on Drugs and Medical Devices (2010)

By-laws and sub-laws (about 40 based on system laws):

- Law for communicable diseases
- Law on sanitary inspection
- Regulations based on the Law on Medicines
- Red Cross Law
- Regulation on Co-payment fees (personal contribution of the insured population in health care expenses)
- Network of health institutions
- Continuous Quality Improvement
- Licensing, accreditation and CME





## Recent Developments in Patient Involvement in the EMA

*Lise Murphy, co-chair of the PCWP and a patient representative of EURORDIS  
and Christoph Thalheim, EMSP representative at PCWP*

During the period 2007 to 2010, patient involvement in activities at the European Medicines Agency expanded substantially – from just 76 patients participating to more than 300 interventions. Patients became active in Scientific Advisory Group (SAG) meetings, safety communications, consultations for both the Committee for Medicinal Products for Human Use (CHMP) and the Scientific Advice Working Party (SAWP), and in workshops and conferences. A particularly important development has been the recognition of patients as “experts” in high-level meetings. As noted below, 2010 marked a real turning point in the level of patient involvement.

Patients now serve the EMA in many roles. Some act as full members of the Management Board (MB), the Committee for Orphan Medicinal Products (COMP), the Paediatric Committee (PDCO), the Committee for Advanced Therapies (CAT) or the Patients and Consumers Working Party (PCWP). Others play a role as Observers of the Pharmacovigilance Working Party (PhVWP) and, from July 2012, the Pharmacovigilance Risk

Assessment Committee (PRAC).

As those who live with disease, patients provide invaluable contributions to the review of product information, including EPAR summaries, package leaflets and safety information (Q&As). Their ad-hoc collaboration in the CHMP supports input on product assessment and the preparation of guidelines.

Their experience is also valuable to experts in the areas of scientific advice/protocol. Involvement in other initiatives – such as the European Network of Centres for Pharmacoepidemiology and Pharmacovigilance (ENCEPP), Eudravigilance (a data-processing network and management system for reporting and evaluating suspected adverse reactions), and the European Network of Paediatric Research at the European Medicines EnprEMA – is equally important. EMSP is pleased to be involved in EMA activities through the Working Party with Patients’ and Consumers’ Organisations (PCWP), which focuses on improving transparency, information on medicines, pharmacovigilance and interaction

with scientific committees.

In 2009 and 2010, patients were involved in reviewing about 60 European Public Assessment Reports (EPARs) and over 130 package leaflets. Of particular importance to PwMS was the opportunity to have a voice in EMA activities related to Tysabri, Fampyra and a transatlantic workshop on PML.

The EMA reports that both patients and consumers see the benefits of being involved and having a voice in regulatory matters. The positive impacts are evident in both quantity and quality of outputs. Based on the success of the EMA model of working with patients and consumers, a similar initiative was launched by the Heads of Medicines Agency (HMA)<sup>1</sup> in April 2011.

To further enhance the role of patient experts, the EMA recognises the need to expand the patient networks at the national level (which requires additional resources) and to provide “EMA literacy training” to help patients better understand complex issues.

<sup>1</sup> The HMA is a network of the Heads of the National Competent Authorities whose organisations are responsible for the regulation of Medicinal Products for human and veterinary use in the European Economic Area.

# Workshop Summaries

## Workshop A | EUREMS: Background, Structure and Expected Outcomes

*Dr. Jaume Sastre-Garriga, CEM-Cat, Barcelona and  
Dr. Tsveta Schyns-Liharska, EMSP*

European patients, including PwMS, face huge inequalities in terms of access to treatments and care, quality of life, etc. They also live under a wide range of socio-economic factors: geographic location, living and working conditions, education, income, etc. In a Europe built on values such as solidarity and equity, this is unacceptable.

At present, this situation is exacerbated by a widely recognised lack of data on: disease epidemiology (including age- and gender-specific trends); access to disease-modifying and symptomatic treatments; long-term efficacy, safety and cost-effectiveness of DMDs; societal costs and how to best allocate socioeconomic resources; degree of access to health care services and their quality; and the quality of life priorities of PwMS.

By developing the European Register for MS (EUREMS), EMSP aims to both enhance the data and information available about individual PwMS and the entire MS community across Europe.

The vision for EUREMS is to:

- provide the infrastructure for data collection, data analysis, interpretation and dissemination of results in MS with European cross-border validity;
- serve as a tool for epidemiological surveillance of MS in Europe; and
- ultimately support PwMS and their carers in their daily lives as well as MS health professionals and the scientific MS community at large.

EUREMS is truly European in scope and multidisciplinary in its approach, involving experts from patient organisations, the clinical community, universities in many countries, as well as various pan-European organisations. Over the next three years, important milestones are set out to develop and test the register, with the aim of using it to help design new research projects by 2014.





## Workshop B | Certified Online Training for MS Nurses in Europe

Anne Winslow, EMSP Vice-President

Following the MS-NEED Survey (carried out in 2011), EMSP has been leading a pan-European initiative to enhance recognition of the role of MS nurses and to unify their knowledge and expertise through certified training. A key aspect of this project is the online delivery of training, which broadens access and is well-tailored to individuals who are already working as professional nurses. Increasingly, both health professionals and MS patients acknowledge the key role MS nurses can play within a multi-disciplinary team (MDT).

In fact, bringing MS nurses directly into the relationship between neurologists and patients establishes mechanisms and links to enhance care, and thus outcomes. The MS-NEED survey found that MS nurses play a central role in the long-term treatment of PwMS and often provide significant support, which has a positive effect on both coping and compliance. The presence of an MS nurse significantly reduces the neurologist's workload and is also cost-effective for health systems.

The MS-NEED Survey identified three key findings and set relevant recommendations:

Finding	Recommendation
Role of MS nurses is evolving and expanding	Recognise MS nursing as a specialty across Europe
Best practice sharing can enhance MS nurses' role within the MDT	<ul style="list-style-type: none"> <li>Need for shared MS nursing educational events/opportunities/resources across Europe in range of settings that include web technology &amp; social media</li> <li>Ensure there is a structured, formalised and improved partnership working within current European forums and international organisations</li> </ul>
Tools and education are needed	<ul style="list-style-type: none"> <li>Need for a stepwise professional development structure against an agreed European definition for MS nursing</li> </ul>



The pan-European unification of MS nurses will increase quality of care for people with MS and their families, and will also directly address the **European Commission's Green Paper: Modernising the Professional Qualifications Directive (2005/36/EC)** – focused on preparing for mutual recognition of a national degree (such as an MS nurse exam) across all member states.

The MS Nursing Project is a collaborative effort of EMSP, Rehabilitation in MS (RIMS) and the International Organisation of MS Nurses (IOMSN).



In cooperation with:







## Workshop C | MS Barometer and UNDER PRESSURE: Living with MS in Europe

*Elisabeth Kasilingam, Marilyn Smith, Walter Astrada, Fernando Molerés, Lurdes Basolí, Maximiliano Braun, Carlos Spottorno and Jesús Mora López-Almodovar (PwMS)*



Despite advances in some areas in some countries, overall the MS Barometer results of 2011 show a downward trend against 2009. What is unchanged is that huge discrepancies exist among countries, which means that a large number of PwMS in Europe do not have the same opportunities for treatment, care and independent living.

In the autumn and winter of 2011/12, a team of five photojournalists travelled to 12 countries<sup>1</sup> to capture how health and social policy influences – **for better or worse** – the daily lives of PwMS. The team worked closely with the MS societies, and was thus able to identify individuals whose situation reflects the positive and negative aspects of each country.

At the two extremes, the team saw first-hand the profoundly negative impact of inadequate policy in Belarus and the ways in which policies that support independent living empower PwMS in Iceland and Germany.

The MS Society of Belarus estimates that 500 PwMS live in the capital city of Minsk. None have access to DMDs or to rehabilitation, and many reach advanced stages of disability at very young ages. Moreover, Soviet-style apartments and poor infrastructure are substantial barriers to mobility. The Society believes that about 430 of these people are rarely able to leave their apartments, and live in a state of poverty because of low disability pensions.

By contrast, MS-félag Íslands (MS Society of Iceland) is able – through government support – to operate a day centre that can accommodate 40 PwMS each day. Aside from providing services ranging from rehabilitation to psychotherapy, the Centre has facilities for recreational activities. In many ways, it serves as a community Centre for PwMS living in Reykjavik. The city is equally remarkable for its accessibility legislation, which makes it easy for PwMS to travel on electric scooters or in wheelchairs.

Germany is equally noteworthy for its high-level of access to therapies, and for the exceptional rehabilitation programmes offered at the Quellenhof Centre. A large number of PwMS (primarily those with additional private health insurance) are eligible to spend 1 to 3 weeks at the Centre each year, where a multidisciplinary team develops a programme that focuses on the patient's current needs and personal goals.

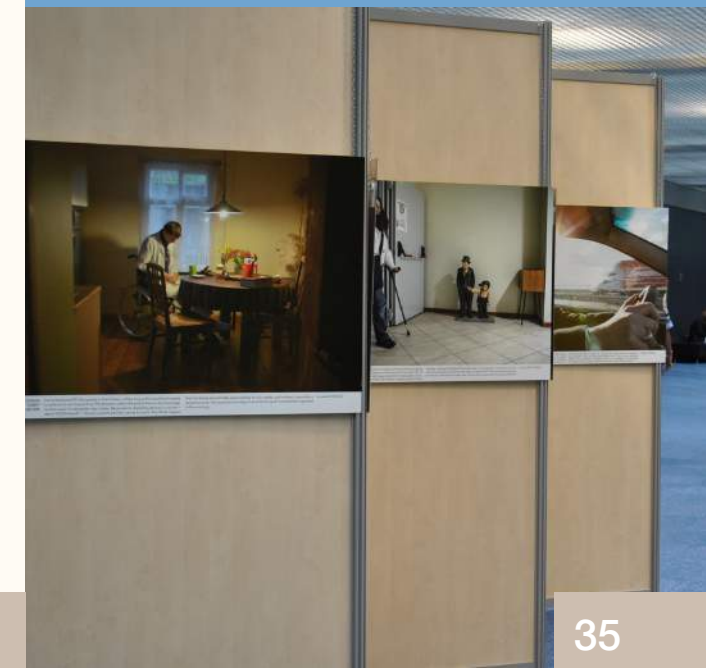
**Jesús Mora López-Almodovar** told workshop attendees that he chose to participate in the UNDER PRESSURE project because he felt MS remains poorly understood by both the general public and by policy makers. Allowing everyone to see into his daily life is a way to send important messages that may help to improve the situation for fellow patients in Spain and across the European Union.

The photographers confirmed Jesus' perception: all admitted that before becoming involved in the project, they had very little exposure to MS. Now, they have friends with MS who are quite

likely to have very different quality of life, simply as a result of which European country they live in. The photographers are united in their desire to use this project to bring media attention to the situation of PwMS across Europe.

The project aims to launch various awareness-raising products and activities in early 2013, to help mark the 20<sup>th</sup> anniversary of the approval (by the US Food & Drug Administration) of the first drug shown to be effective for MS.

1| Belarus, Estonia, France, Germany, Greece, Iceland, Ireland, Italy, Poland, Spain, Romania and the United Kingdom.





# EMSP Youth Congress 2012

## Report

### Introduction

Emma Rogan, Ireland, Chairwoman of the 2012 Youth Conference.



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Carrying on the successful gatherings in 2010 and 2011, the EMSP Youth Congress continues to be an opportunity for representatives from all over Europe to share experiences, discuss different issues and to create plans for positively changing the experiences of Young People with Multiple Sclerosis (YPwMS) in their home countries and in Europe as a whole.

Barcelona was the location for the third Youth Congress held on May 19th 2012. It was an opportunity to reflect on the work done since the last two meetings of YPwMS and look to the future work of the group. There were eighteen attendees from thirteen countries: Belgium, Czech Republic, Denmark, Estonia, France, Greece, Ireland, Italy, Lithuania, Netherlands, Norway, Romania and Spain. Gender composition of the group was seventeen women and one man. With such a diverse gathering in terms of nationalities, it was a fantastic opportunity to share different cultural experiences particularly related to the main topics.

Chosen over the last twelve months through online collaboration and following on from previous years, the topics of **Sexuality and Pregnancy when living with MS** were the issues for discussion in 2012.

YPwMS consider these issues very important for their lives now and in the future. Discussing what are sometimes considered private, taboo topics in a clear and openhearted fashion was a way to open up the dialogue for MS societies across Europe. These are topics fundamentally important for all young people, straight, lesbian, gay, with or without MS and they are issues that affect us all on a deep, emotional level.

During the previous twelve months Julie Deléglise, EU Affairs and Membership Officer at EMSP, liased with a group of people from the Youth Congress. Following questionnaires, teleconference interviews and careful collaboration, a video about these issues was produced. **Sexuality and Pregnancy with MS** is a short film showing the experiences of a young woman as she deals with

MS in her daily life as an individual, as a worker, as a partner and as a mother.

The film had a profound effect on many people at the Youth Congress - it was true to people's experiences as well as humorous - and proved to be an excellent way to open up the discussion of topics that, due to cultural and social taboo, many thought had been ignored and not treated with enough consideration.

This video is available at [www.emsp.org](http://www.emsp.org)



## Sexuality and MS

*Marjan, The Netherlands*



Be careful if you look for advice on internet. There is plenty of information on the Internet, but there is a question of whether this information is always reliable.



Take it easy and relax!



There are NO major sexual difficulties, only lack of imagination!

Before starting to talk about sexuality we saw the movie “Sexuality, Pregnancy and MS”. I invite you to watch it: [www.emsp.org](http://www.emsp.org). We discovered the movie is a fantastic tool to start discussions about sexuality, pregnancy and MS. We all like to know about these subjects and enjoy a nice sex life, but to talk about sex...that is another story. It was a significant film for many of the participants, causing a profound effect because the characters portrayed many of the issues faced in the daily reality of life as a YPwMS.

As sexuality is a difficult subject to talk about, we tried to get answers to the following questions:

- Which sexual changes (physical and psychological) do young people with MS have to face?
- How to cope with these changes?
- What are the strategies to better communicate with your partner, lover, friends, doctors, health care professionals, sexologists?
- to recover and enhance body image, self-worth and sexual confidence? to have a fulfilling sexual life (use of sex toys, dildos, lubricants, body

mapping...)

- Do national MS societies provide support and/or counselling to young people with MS regarding intimacy and sexuality?

A lot of YPwMS seem to have problems with fatigue, loss of sensitivity/sensibility, cramps and tension. Even the thoughts of having cramps during sex cause difficulties and are a common problem.

Talking to your partner is a major issue. As problems are common when we have sex, they are not the same issues every time and might not be an issue at other times. MS can be a problem in a relationship, but do not make MS the most important thing in the relationship. We have discovered that partners of YPwMS are often forgotten. Partners may think that they are the problem, when actually it is other issues that are causing their partner with MS the difficulties. Without communication, it is very easy for our partners to misunderstand what the issues are and to know that they are not the cause of them.

Often, it is the lack of communication about the issues (fatigue, cramps, poor body image) that is the cause of sexual issues.

Of course we need to focus on a good life together. A quality weekend for the couple once a month for instance. Children are out of the house, spending a lovely time at their grandparents, and creating a romantic atmosphere.

Being positive, having fun and enjoying the pleasures of sex is very important and is something that needs to be planned. Having lunch in a nice restaurant, walking in a park, swimming in the sea, go to the cinema and watch a nice movie, buy flowers...things that make the other person feel loved and special is a vital part of ensuring the sexual aspects of a relationship are given opportunities to flourish.

There are cultural as well as personal issues that might prevent people from talking about their sex lives to their neurologists, doctors, or other healthcare professionals. Also, because positive

sexual health is often not discussed by health professionals, YPwMS get the impression that it is not important. If healthcare professionals were willing to discuss the issues of sexuality and pregnancy, YPwMS would be more open and have the opportunity to fully discuss the impact MS has on our sex lives.

Our national MS societies provide some information about sexuality in brochures, small newsletter columns, on Facebook and their own website. It was suggested that future workshops about sexuality should be planned with other topics included.

Love yourself and love each other. When sex happens it happens, but it is all about a good time together. Look for ways to do the things you enjoy most with the people you like the most!



Love yourself, know your body and use sex toys!





## Pregnancy and MS

Isabella, Belgium

*“It’s a paradox. How does one balance living in the now with preparing responsibly for the future? The key to this dilemma lies in the distinction between ‘worrying about the future,’ and ‘preparing for the future.’ The two concepts are not at all the same.”*  
Jonathan Lockwood Huie

To kick off this workshop, the 18 participants were asked whether they have children or not:

- There were three YPwMS with children;
- One YPwMS was five months pregnant;
- There was one man present in the group and his wife was pregnant;
- Some YPwMS had a dilemma about whether to have children;
- Other YPwMS were sure they definitely wanted to have children.

Knowing this, I could finally begin to start the discussion. The following points were discussed:

- Due to treatment, do persons with MS face infertility?

- Is pregnancy causing new symptoms?
- Is pregnancy worsening the condition? To what extend?
- Do pregnant women with MS have to stop their treatment during their pregnancy?
- By choosing to have children, do people with MS feel guilty? Selfish? By choosing not to have children, do people with MS feel guilty/ selfish? What are their concerns?
- Where does research stand with MS and heredity?
- Strategies to communicate with the partner, the relatives, friends, doctors?

Some of these questions were handled very easily. Others were more difficult to discuss. We all have MS with personal experience of the condition. However, we are not doctors or professors. We cannot give exact information on some points; we can only clarify certain aspects by using our experience. A psychologist in the group shared her experience and advice regarding some points raised in the discussion.

The three mothers in our panel all shared their experiences. It was a big advantage to have these mothers among us, because a lot of us are still struggling with the dilemma of whether or not to have children.

They were clear: they did not face any new symptoms. During their pregnancy, they felt similar to how they were before they were diagnosed with MS. They recovered skin sensitivity, the tingling in their hands/feet/limbs had gone, fatigue levels improved as well as many other positive effects. They all were in good condition. According to the testimonies, pregnancy can have a significantly positive influence on the woman’s MS.

The group agreed that it is necessary to stop the treatment(s) during pregnancy. But, anecdotally, there was a known person with MS, who did not know she was pregnant until she gave birth to a healthy son! The baby boy was examined but there was no problem at all. Was this an exception? We suppose so. We still shared the same opinion that it is “advised” to stop treatment. Something

else that we need to consider.

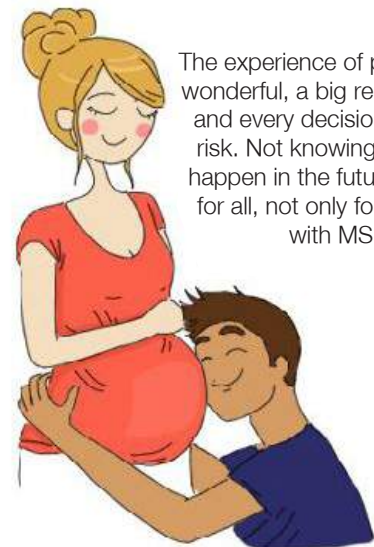
There was a discussion about being selfish or being guilty when choosing whether or not to have children. Someone in the group immediately shared her opinion, “When you try to get pregnant, it is not selfish at all to continue your treatment”. Everyone agreed. But then the discussion started again on “What if you don’t know yet if you’re pregnant?”

Some thought PwMS should stop their treatment a few months before they get pregnant due to the potential side-effects on the foetus. Following this, another point of discussion started: “What/ who can we count on during pregnancy and when the child is born?”

Someone came up with a brilliant idea for couples to plan quality time together. Asking relatives or friends to take care of the children during a weekend, so the person with MS can have some rest and the couple can have uninterrupted opportunity for their relationship.



Don’t be ashamed, talk openly to your partner about your feelings regarding having children.



The experience of parenting is wonderful, a big responsibility and every decision involves risk. Not knowing what will happen in the future is a risk for all, not only for persons with MS!

#### The partners of YPwMS

A lot more needs to be done and organised for partners who face MS every day, deal with the symptoms, the difficulties and the issues! We can try to organise some meetings (small and bigger ones) to let them discuss. We can do it on a face-to-face base, but it can also via alternative meetings or other ways. To end this workshop, I was wondering whether this whole discussion did change something about the doubts of the people with no children: most of them were sure to have children before the discussion. But another few still face their dilemma...

We also referred to the realistic short film, shown at the start of these workshops. It showed a few situations during and after pregnancy and gave some reasonable solutions – ways of helping, supporting the partner of the pregnant PwMS; the parents and close relatives; close friends. There are some services which you can count on after giving birth which offer help with the child and help you to manage your housekeeping.

We do not know exactly where this research stands. What about the effects of treatment on the pregnancy? We all agreed that it must not be good. But a lot more research on this needs to be done. What about these children when they grow up? Will they get sick? Does it influence their health? So far, we did not hear a negative story on this issue. But we agreed that research certainly must be continued!

We also agreed about the focus on the use of hormones. They seem to have a positive effect on pregnant women with MS.

We all agreed that the video on Sexuality, Pregnancy and MS will be a “must have” in every MS environment! Social workers, social nurses, the MS communities, the neurologists, everyone in the field MUST see this film and they must spread it via websites, Facebook, meetings, conferences and workshops.

## The Italian Experience

*Silvia and Federica, Italy*

#### Women’s project

The Italian MS Society (AISM) has thought up a specific project focused on the implications and aspects that are typical for women, and paying special attention to what it is like to be a woman with MS. The aim is to provide accurate tools for women with MS and create with them a direct channel for understanding and monitoring their needs. The project proposes various innovative ways to focus on all topics of interest to women with MS, and involving women, who may then take on active roles.

Launched in 2007, the project anticipates the organisation of seminars - for women only on the subject to promote the dissemination of accurate and up to date information, and foster dialogue and debate. These will be reinforced by the creation of an archive of videos online on topics chosen directly by women with MS and the publication of books on topics specific to women. This project will also encourage the sharing of experience - the telling of personal stories that can help understanding what it means for a woman to live with MS.

#### Couples and family projects

MS is a complex disease that affects not only the individual but also people who are around him or her, in all aspects of everyday life, from the emotional to the practical. The family has long been the focus of projects run by the MS Society, which aims to provide valuable support for people with MS and their families. By comparing the experiences of those who live every day with MS it was possible to collect and identify the main difficulties that families can encounter, with many of the initiatives designed to address their specific needs.

The project includes several activities: information sessions, opportunities for socialising with MS and the sharing of expertise, training sessions, and publications. In particular, it is planned to organise annually:

- A 4 day stay at the Holiday House in the Sunflowers Lucignano during which families will have the opportunity to meet with professionals, such as neurologists, social workers, employment law experts, psychologists, and physical therapists to discuss major concerns and issues related to







## Conclusion

*Emma Rogan (Ireland)  
Chairwoman of the 2012 Youth Conference*

MS. The formal sessions are accompanied by information activities for relaxation and recreation for adults and children.

- Weekends for couples spent with a psychologist to examine the internal dynamics of the couple living with MS.
- Training meetings for organizing self-help groups to promote opportunities for sharing, exchange of experiences and information among peers.
- These activities are connected to the continuing need to produce appropriate publications for the family, either downloadable from the website or found in the library.

### Web Quiz

AlSM has a new information tool: a series of Web quizzes on specific disease topics, to increase knowledge, recount the experiences of people with MS, dispel doubts and facilitate comparison. Web quizzes are useful for testing yourself, answering questions on everything about MS, reading in detail, writing reviews and if possible passing the quizzes. If you get the wrong answer, you can read the right answer, with a small explanation, below the questions.

Multiple sclerosis affects not only the individual but also the partner, the lover, the family, the friends and all those who experience the repercussions of life with MS. Communication is one of the most valuable tools we have to create change. It is by being strong together, nurturing one another and being active participants in our lives that the needs and issues of life can be dealt with.

Using the personal experiences and the strategies developed, the EMSP Youth Congress wants to ensure that the topics of sexuality and pregnancy will be considered as important as other issues.

It is from the discussions of MS and sexuality and pregnancy in an open way that YPwMS will create a resource pack applicable to all European MS societies. The relationships formed during the first EMSP Youth Congress in 2010 continue to flourish and we all look forward to a better future for YPwMS in Europe.



Busy with a quiz...



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