

Risk of Infections in MS DMTs

The aim of the workshop is to review the short- and long-term risks of infections associated with the MS treatments as well as the risks associated with treatment sequencing. We will also focus on specific populations such as children and senior patients with advanced disease or geographically diverse populations coming from high infection burden regions. Strategies to detect and if possible prevent infections, including vaccinations, will be addressed.

THURSDAY, 12 MARCH 2020

- 08.30 - 08.45** **Welcome**
B. Stankoff (Paris, FR)
- 08.45 - 09.15** **Introductory Session: General overview of safety issues in MS treatments in 2020**
A. Boyko (Moscow, RU)
General overview of safety concerns related to MS DMTs with special focus on autoimmunity, cancer and rare serious events
- 09.15 - 10.30** **Session 1: Current data on infections in relation with MS treatments**
Chairs: K. Selmaj (Olsztyn, PL), M.P. Amato (Florence, IT)
- 09.15 PML risk and prevention
Y. Taoufik (Paris, FR)
PML prevalence, immune mechanisms of JCV surveillance and clearance, risk stratification, biomarkers. PML risk beyond natalizumab treatment (dimethyl fumarate, fingolimod, ocrelizumab, rituximab)
- 09.35 Discussion
- 09.40 PML management and treatment
D.B. Clifford (St Louis, US)
Early diagnosis of PML. How to treat PML in MS including PE and steroids, immune checkpoint blockade; other perspectives?
- 10.00 Discussion
- 10.05 Infections when using S1P modulators
M. Mehling (Basel, CH)
MoA, type of immunity impaired, rate of infections and specific infections reported, with a specific focus on VVZ infections. Please review fingolimod, siponimod, ponesimod, ozanimod. Risk mitigation strategies: what needs to be monitored (lymphocytes count, other, possible preventive strategies or treatments)

- 10.25 Discussion
- 10.30 - 11.00 Coffee break**
- 11.00 - 12.40 Session 1: Current data on infections in relation to MS treatments (continued)**
Chairs: K. Selmaj (Olsztyn, PL), M. P. Amato (Florence, IT)
- 11.00 Infections when using lymphodepleting therapies: CD52 therapies
K. Selmaj (Olsztyn, PL)
MoA, type of immunity impaired, rate of infections and specific infections reported, with a specific focus on bacterial infections (TB, listeria), and viral infections (CMV, herpes), lessons learned from previous use of alemtuzumab on other indications. Risk mitigation strategies (what needs to be monitored (lymphocytes count, other, possible preventive strategies or treatments). [Please note that fungal infections and VPH prevention will be addressed in other talks]
- 11.20 Discussion
- 11.25 Infections when using lymphodepleting therapies: cladribine, dimethylfumarate and teriflunomide
P. Soelberg Sørensen (Copenhagen, DK)
MoA, type of immunity impaired, rate of infections and specific infections reported, with a specific focus on bacterial infections (TB), and viral infections (Varicella zoster infection, herpes simplex virus). Risk mitigation strategies (what needs to be monitored (lymphocytes count, other, possible preventive strategies or treatments). [Please note that PML will be addressed in a previous presentation]
- 11.45 Discussion
- 11.50 Infections under anti CD20 therapies
F. Piehl (Stockholm, SE)
MoA, type of immunity impaired, rate of infections and specific infections reported, with a specific focus on HBV reactivation, lessons learned from previous use of anti-CD20 therapies on other indications. Please review rituximab, ocrelizumab and ofatumumab.) and discuss risk mitigation strategies
- 12.10 Discussion
- 12.15 Infections under new NMOSD treatments: anti-CD 19 (Inebilizumab); Eculizumab and Satralizumab
B. Weinshenker (Rochester, US)
MoA, type of immunity impaired, rate of infections and specific infections reported. Risk mitigation strategies
- 12.35 Discussion
- 12.40 - 14.00 Lunch break**

- 14.00 - 15.15** **Session 2: Infectious risks in specific populations of MS patients planning to start or already receiving immunosuppressive or immunomodulatory treatments: what should we do?**
Chairs: A. Vaknin-Dembinsky (Jerusalem, IL), A. Siva (Istanbul, TR)
- 14.00 Paediatric population
Y. Hacoheh (London, UK)
Infections and specific infections reported. Risk mitigation strategies
- 14.15 Pregnant women
R Dobson (London, UK)
Infections and specific infections reported. Risk mitigation strategies
- Immigrant populations from high infection burden regions:
Infections and specific infections reported. Risk mitigation strategies
- 14.30 Infectious risks in specific populations Latin America
L. Negrotto (Buenos Aires, AR)
- 14.45 Infectious risks in specific populations: India/Asia
L. Pandit (Mangalore, IN)
- 15.00 The role of comorbidities and advanced age on the risk of infections
K. Fitzgerald (Baltimore, US)
Which comorbidities that may increase the risk of infections? Special concerns in senior patients
- 15.15 - 15.45** **Roundtable/Panel discussion Session 2**
Do we have to adapt our preventive strategy for infection in specific populations?
- 15.45 - 16.15** **Coffee break**
- 16.15 - 17.30** **Session 3: Facing complex situations in the management of infectious risks**
Chairs: L. Brundin (Stockholm, SE), Anat Achiron (Tel Aviv, IL)
- 16.15 Fungal infections: is there a need for prophylaxis?
I. Ruiz (Barcelona, ES)
What is the risk for fungal infection in treated MS patients and what infections are most prevalent? Is fungal prophylaxis needed for all MS treatments? When should it be started? How long is the prophylaxis needed?

- 16.35 Discussion
- 16.40 Hypogammaglobulinemia: a misleading sign?
T. Derfuss (Basel, CH)
Is hypogammaglobulinemia frequent under anti CD20? Could it also present with other treatments? Does it really increase the risk of infection? Should patients receive IVIg to prevent infections?
- 17.00 Discussion
- 17.05 Risks of infections in treatment sequencing
D. Baker (London, UK)
Are DMTs inducing long lasting immune effects? Do prior treatments have an impact on increasing the risk of infection with subsequent treatments?
- 17.25 Discussion
- 17.30 - 17.45 Wrap up Day 1**
D. Karussis (Jerusalem, IL)
- 19.30 Focused Workshop Dinner**

FRIDAY, 13 MARCH 2020

- 8.30 - 10.00 Session 4: Prevention strategies: vaccination**
Chairs: M. Farez (Buenos Aires, AR), E. Ganelin-Cohen (Petah Tikva, IL)
- 08.30 Are vaccines safe and effective in MS patients?
B. Hemmer (Munich, DE)
- 08.45 Overview of vaccination strategy in MS patients and candidates for MS-related treatments
S. Otero (Barcelona, ES)
General preventive strategy before starting treatment. How to deal with already immunocompromised patients, can we speed up immunizations
- 09.00 Safety and utility of vaccines when used in patients already receiving specific MS treatments
S. Vukusic (Lyon, FR)
Vaccinations for already treated patients: which are counterindicated/which are recommended?

- 09.15 Recently available vaccines with potential benefit in MS patients under immunosuppressive therapy: *lessons from other fields*
A. Winkelmann (Rostock, DE)
Herpes zoster vaccine - Possible use of the inactivated herpes zoster vaccine in patients over 50 years of age with previous exposure to varicella virus. Human papillomavirus virus vaccine - What would be the potential recommendation for HPV vaccine in MS patients.
- 09.30 Vaccine recommendations for international travel
C. Hatz (Basel, CH)
Preventive strategies and special precautions for international travel for MS patients using immunosuppressive therapies
- 09.45 Yellow fever vaccination and multiple sclerosis.
C. Papeix (Paris, FR)
Is there a specific risk for yellow fever vaccination in MS? Which recommendation for patients with MS, without treatment or with specific therapies
- 10.00 - 10.30 Roundtable/Panel discussion Session 4
Should we recommend vaccination against VZV, HBV, HPV early in MS disease course for non-immunized patients?**
- 10.30 - 11.00 Coffee break**
- 11.00 - 12.00 Session 5: Future strategies and recommendations to improve data collection and infectious risk management
Chair: S. Vukusic (Lyon, FR), C. Enzinger (Graz, AT)**
- 11.00 Experiences from registries and observational studies: what is ongoing and what needs to be done
M. Trojano (Bari, IT)
How to improve infection surveillance, prevention, and management through MS registries
- 11.15 How to improve infection prevention, detection, and management through international adverse event reporting: the role of regulatory agencies
E. Martinez-La Piscina (Barcelona, ES)
The role of EudraVigilance as a single repository for reports of suspected adverse reactions seen in healthcare practice and clinical trials.
- Final recommendations for the management of infectious risks in routine clinical practice.
- 11.30 Recommendation from an MS expert point of view
L. Kappos (Basel, CH)
What needs to be done before starting treatment and during treatment? The role of nurses, the role primary care physician.

- 11.45 Recommendations from an infectious disease expert point of view
D.J. Epstein (Palo Alto, US)
What needs to be done before starting treatment and during treatment. The role of infectious disease specialists and preventive medicine specialists
- 12.00 - 12.20** **Wrap of Day 2**
B. Stankoff (Paris, FR)
- 12.20 - 12.45** **Meeting Summary**
M. Tintoré (Barcelona, ES)
- 12.45** **Lunch and individual departure**