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Future Perspectives

COVID-19 in people with multiple sclerosis: A global data sharing initiative

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Abstract

Background: We need high-quality data to assess the determinants for COVID-19 severity in people with MS (PwMS). Several studies have recently emerged but there is great benefit in aligning data collection efforts at a global scale.

Objectives: Our mission is to scale-up COVID-19 data collection efforts and provide the MS community with data-driven insights as soon as possible.

Methods: Numerous stakeholders were brought together. Small dedicated interdisciplinary task forces were created to speed-up the formulation of the study design and work plan. First step was to agree upon a COVID-19 MS core data set. Second, we worked on providing a user-friendly and rapid pipeline to share COVID-19 data at a global scale.

Results: The COVID-19 MS core data set was agreed within 48 hours. To date, 23 data collection partners are involved and the first data imports have been performed successfully. Data processing and analysis is an on-going process.

Conclusions: We reached a consensus on a core data set and established data sharing processes with multiple partners to address an urgent need for information to guide clinical practice. First results show that partners are motivated to share data to attain the ultimate joint goal: better understand the effect of COVID-19 in PwMS.

Keywords: Multiple sclerosis, pandemics, COVID-19, data collection, registries, coronavirus 2, humans

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Introduction

There is uncertainty as to the specific risks of COVID-19 in people with multiple sclerosis (PwMS), in particular, whether taking immunosuppressant or immune-modifying medications affect COVID-19 course or outcome. With the current lack of robust data, approaches to the clinical management of MS during the pandemic diverge between countries. To overcome the insecurity, now and in the future, various COVID-19 data collection initiatives have recently been developed.[1] However, because of the relatively low prevalence of MS,[2] the absolute number of symptomatic COVID-19 infection in people also affected by MS is likely to be relatively low. This reduces the ability of single registries to achieve significant insights via individual national efforts. International data sharing is likely to enable more rapid evidence generation that will help to guide clinical management during the pandemic and may support future research. The Multiple Sclerosis International Federation (MSIF: https://www.msif.org/) and the Multiple Sclerosis Data Alliance (MSDA: https://msdataalliance.com/) have teamed up with multiple partners to establish a global data

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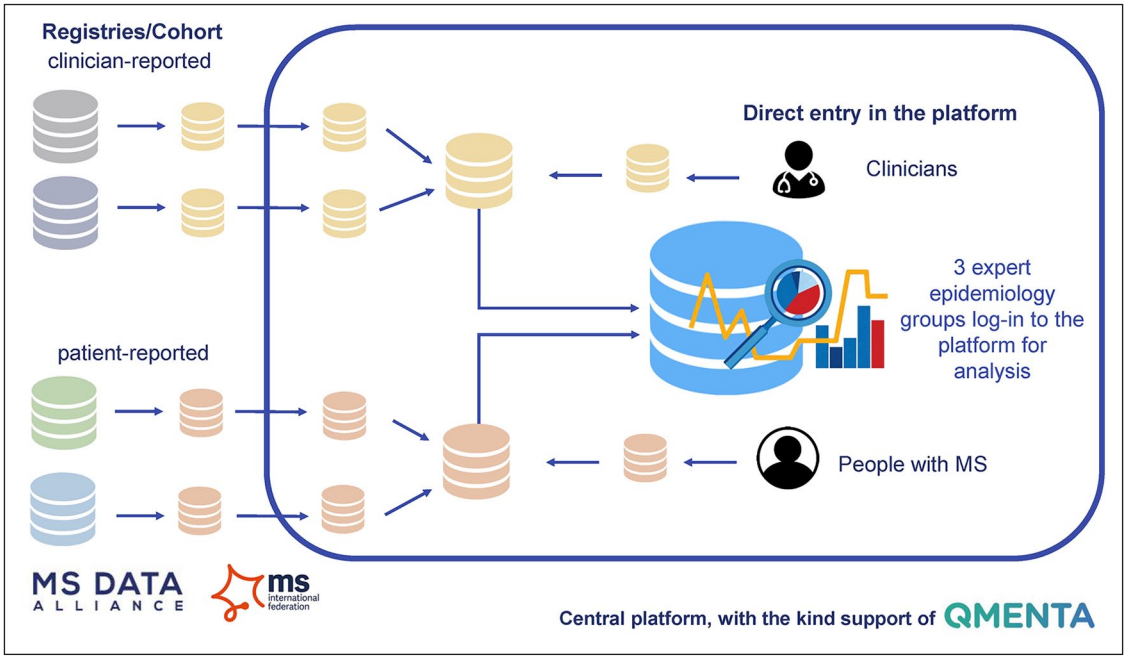

Figure 1. High-level overview of the COVID-19 in MS-global data sharing initiative: we recommend the implementation of the COVID-19 in MS core data set in as many different data initiatives (registries/cohorts) as possible. All initiatives are invited to regularly share de-identified COVID-19 in MS core data sets into the central platform. In parallel, direct entry of individual PwMS and clinicians in the central platform is possible. The data sources are combined within the platform and the expert epidemiology groups check the quality of the data sources. Once a certain threshold of trustworthiness of the data and the results is met, the platform will become interactive and feed back results to the community.

sharing initiative (in short 'initiative'). This paper explains the steps taken and direction proposed for this effort.

The overall approach of the global data sharing initiative

The ultimate driving research question of the initiative is to understand the effect of individual disease-modifying therapies (DMTs) on COVID-19 outcomes. We aim to feed back results as rapidly as possible to the community and to inform evidence-based global guidance for PwMS and healthcare professionals during the pandemic. Time is of the essence here. Therefore, a pragmatic approach was defined and developed. Figure 1 summarizes the high-level overview of our approach. The approach we propose is compliant with all legal and ethical restrictions relating to data collection and data sharing.

Global alignment on a COVID-19 in MS core data set

To prepare the draft COVID-19 in MS core data set, we started with identifying common areas of interest in emerging and active data collection efforts on COVID-19 in MS. A final list of variables was agreed to within 48 hours in a global consensus-building teleconference. The core variable set can be downloaded via the MSDA website (https://msdataalliance.com/covid-19/for-ms-registers-and-data-custodians/). The following groups of variables were deemed important: COVID-19 infection, COVID-19 severity, COVID-19 treatment, demographic information, MS history and severity, information on DMT use and comorbidities and selected lifestyle behaviours, particularly smoking. During the consensus-building teleconference, we agreed on the importance of including both patient-reported and clinician-reported data to facilitate the inclusion of both milder and more severe COVID-19 cases in MS.

Working through the global MSIF movement to encourage widespread recording of COVID-19 in PwMS

The success of this initiative requires widespread activation of the global MS community to record the COVID-19 status of PwMS. The global recommendations for PwMS and healthcare professionals can be consulted on our websites. Our communications approach centers on working with national and

Table 1. Currently participating COVID-19 in MS data collection initiatives.

COVID-19 in MS data collection initiative	Patient-reported data collection	Clinician-reported data collection
ABEM	Yes	No
AMSLS	Yes	No
Australia and New Zealand COVID-19 data set	No	Yes
Bulgarian SmartMS COVID-19 data set for patients or clinicians	Yes	Yes
Cleveland Clinic MS COVID-19 Registry	Yes	Yes
COViMS Registry, a North American COVID-19 and MS Reporting Database	No	Yes
EMA COVID-19 survey	Yes	No
French COVISEP[4]	No	Yes
German MS Register, by the German MS Society COVID-19 Survey	Yes	Yes
HOLISM	Yes	No
Icompanion	Yes	Yes
iConquer MS COVID-19 Survey	Yes	No
LEOSS Registry	No	Yes
MSBase COVID-19 Sub-study	No	Yes
NeuroTransData	Yes	Yes
OptimiseMS	No	Yes
REDONE	No	Yes
RELACOEM	No	Yes
Swedish MS Registry COVID-19 Module	No	Yes
The Danish Multiple Sclerosis Registry	No	Yes
The Spanish MS Registry	No	Yes
UK MS Register COVID-19 CRF	Yes	Yes

COVID-19: Coronavirus Disease 2019; MS: multiple sclerosis; ABEM: Brazilian Multiple Sclerosis Association; AMSLS: Australian MS Longitudinal Study; COViMS: COVID-19 infections in MS database; EMA: Esclerosis Multiple Argentina; COVISEP: part of French MS Registry collecting data on COVID-19; HOLISM: Health Outcomes and Lifestyle In a Sample of people with Multiple sclerosis; LEOSS: Lean European Open Survey on SARS-CoV-2 infected patients; REDONE: Brazilian Registry of multiple sclerosis and neuromyelitis optica spectrum disorders; RELACOEM: part of RelevarEM registry that will collect the data of COVID-19; CRF: case report form.
Currently, there are 11 registries/cohorts collecting (or preparing to collect) patient-reported data and 18 registries/cohorts collecting (or preparing to collect) clinician-reported data.

regional MS organizations across the global MSIF movement to create and share specific content for their stakeholder networks. We invite all MS societies and patient organizations to join the initiative by encouraging PwMS and healthcare professionals across their networks to record data.

Implementation of the COVID-19 in MS core data set in as many existing and emerging registries or cohorts as possible

Registries and cohorts are able to deliver the highest data quality. Such high-quality data are needed to deliver fine-tuned results during, but particularly after, the pandemic. Some of these initiatives are already available for international COVID-19 and MS data collection and have implemented standardized safety protocols to address post-authorization safety studies (PASS).[3] Table 1 summarizes the current list of initiatives that have or are planning to implement the COVID-19 in MS core data set (as of 10 May 2020). This list is expanding rapidly and is continuously updated on our websites.

We also provide an option to directly enter data into our central platform (a distinction is made between a clinician-reported fast module for data entry by healthcare professionals (https://platform.qmenta.com/covid19_ms_clinician) and a patient-reported fast module for data entry by PwMS (link: https://platform.qmenta.com/covid19_ms_patient)). The clinician-reported fast module might be of benefit to healthcare professionals who only have the resources to collect the core data set.

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Regular uploads of de-identified COVID-19 in MS core data sets into a central platform

We invite all MS registries and cohorts to regularly share their COVID-19 core data set ('export') into the central platform, kindly provided by QMENTA (https://www.qmenta.com/). QMENTA is a cloud-based platform that allows for the aggregation, standardization, management and visualization of any form of data, with a focus on clinical and imaging data sets. The protocol of this study is approved by the ethical committee of Hasselt University (reference no. CME2020/025). A disclosure risk assessment was performed by an independent third party (P-95: https://www.p-95.com/). To minimize the risk of patient's identity disclosure, we implemented a strict user access management as well as restricted data access to a minimal number of dedicated researchers. Next to this, the data are stored centrally in a secured environment.

Next steps

Regular updates of the progress of the initiative and the data counts are provided publicly on the QMENTA website (https://www.qmenta.com/covid19-patients_ms-table/). Current global COVID-19 advice for PwMS is based on expert opinion but will be revised as soon as data of sufficient quality are available. PwMS and healthcare professionals have a broad variety of questions that need to be addressed as soon as possible. To scope the initiative, we considered the following initial questions expressed as important among patients and organizations:

1. Are PwMS at greater risk for severe COVID-19 outcomes compared to the general population?
2. Is the pattern of risk factors for COVID-19 outcomes similar compared to the general population? (e.g. age, comorbidities, etc.); Does the severity of MS have an effect on COVID-19 outcomes?
3. Is there a difference in COVID-19 outcomes between untreated PwMS and PwMS on DMT?
4. Does the type of treatment have an effect on COVID-19 outcomes?

With the data being collected, which will focus on reported cases of COVID-19 among patients and not assess the background populations, we need to give priority to analyses on cases only, most importantly to identify factors predicting outcome once an infection is suspected or confirmed. In contrast, we believe in-depth analyses of population-based data sources including history and follow-up information will be required to address some research questions, such as risks of COVID-19 in the MS population and contributing factors such as DMTs or the long-term effect on MS progression of having had a COVID-19 infection, which will require a longer term follow-up. We aim to achieve methodological insights during this global data sharing initiative that can stimulate this on-going and future scientific research led by others within the MS community.

Conclusion

The COVID-19 pandemic represents a humanitarian crisis on a colossal global scale and there is evidence that the crisis will not be solved soon, so initiatives to minimize the risks of COVID-19 are fundamental. For people living with MS, it is not only the threat to their health imposed by the virus itself but also the wider impact of reduced access to healthcare and medications that are essential for managing their symptoms, preventing relapses and reducing disability. PwMS and the healthcare professionals providing their care are in urgent need of evidence on which to base challenging clinical decisions. Uncertainty over the true threat of COVID-19 to PwMS has stimulated a cautious approach to preventing infection, including from the clinical community, patients themselves and many governments as well. PwMS are frequently classified as 'high risk' and advised to follow the strictest social distancing measures. These measures have reduced access to routine healthcare, including rehabilitation, exercise and sources of emotional support and as such come with significant risks to physical and mental health. There are several advantages of formulating global recommendations for data collection as rapidly as possible. These include, for example, providing a framework to enable data collection in a wider number of countries and regions; enabling comparative analysis of treatment regimens and outcomes across different countries; and reducing the time and cost of future collaborative research using COVID-19 and MS case data (compared to using retrospective data harmonization efforts).

The prompt establishment of a global data sharing initiative due to the natural urgency is an ambitious undertaking. Nevertheless, we were able to motivate numerous stakeholders in the field of MS (neurologists, patient organizations, researchers, registries, etc.) to join our effort in bringing together data from patients, clinicians, registries and other COVID-19 in MS initiatives. We aim to continuously improve our approach while we move ahead. We hope the data sharing approach used here can be used as a template

for different stakeholders to work together on an international scale also outside of the scope of the COVID-19 crisis. Indeed, there are many other urgent research questions that need to be addressed that require scaling-up real-world data research at a global scale.

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