

Young people with RMDs, Participation, Doctors and Patients as Partners. Furthermore, in 17 podcasts our member organisations highlighted their activities for people with RMDs. Volunteers vividly described their inside view in the podcasts. In addition, we created a historical timeline for the website. Special highlight was a radio programme based on our videos, summarising our activities that was broadcast by 19 radio stations.

**Results:** The video clips attracted more viewers than could have been reached with an event in Berlin. For example we generated 35.000 viewers on our YouTube channel by presenting the birthday speech by our president. Altogether we reached successfully approximately 1.5 million people national wide. I will present the numbers of people our activities reached and feedback we received.

**Conclusion:** We are convinced going on the right track using digital media as one of our priorities not only in times of pandemic but as a valuable enrichment for all RMD patients on national and international level.

These examples of best practise experiences shall encourage other patient organisations to take on the challenge in pandemic times. By using digital tools and formats patient organisations can succeed in reaching more RMD patients and in staying connected with their members.

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### OP0324-PARE PATIENT INFORMATION IN TIMES OF CRISIS: LESSONS LEARNED FROM COVID-19 COMMUNICATION IN RHEUMATOLOGY

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**Background:** The rapid global spread of COVID-19 required swift action to provide people with rheumatic and musculoskeletal diseases (RMDs) with reliable information. Important issues included the risk of infection and severe illness, (continued) use of medication, temporary closure of clinics, and organization of (semi-) virtual care. People with limited health literacy are a particularly vulnerable group that might have difficulty accessing, understanding, and applying health information.

**Objectives:** To evaluate (a) key aspects of crisis communication and (b) explicit consideration of people's health literacy needs in communication to people with RMDs during the first wave of COVID-19 in the Netherlands.

**Methods:** We conducted an explorative qualitative study including seven interviews in May and June 2020 with representatives of organisations (a mixed regional/academic hospital, the association for RMD professionals and two patient organisations) responsible for information provision to people with RMDs in the Netherlands. Interviewees were asked about preparedness (1) and strategy (2) for crisis communication, and content (3) and reach (4) of communication, considering principles of good crisis communication and health literacy. In addition, through systematic screening of websites, social media and emails, we identified and analysed 13 written communications provided to people with RMDs by these organisations during the first three months of the COVID-19 pandemic. We assessed comprehensibility and applicability with the Dutch adapted version of the Patient Education Materials Assessment tool (PEMAT), the outcome being a percentage of adherence to 24 criteria. We assessed difficulty level using an online assessment application (Figure 1), with Common European Framework of Reference for Languages (CEFR) level B1 being the highest acceptable level.

Analysed text	Translation for reference
Wat te doen met reumamedicatie als u verder niet ziek bent?	What to do with your rheumatism medication if you are otherwise not ill?
Het gebruik van reumamedicatie zoals methotrexaat en biologica kan door het werkingmechanisme van deze medicijnen zorgen voor een verminderde afweer tegen infecties. Er zijn nog geen gegevens beschikbaar voor COVID-19 beschikbaar. Als u niet ziek bent is er geen reden om te stoppen met uw reuma medicatie, dit kan uw risico op een opvlamming van de reuma juist verhogen. Het advies is om de medicatie door te gebruiken, waarbij altijd het laagste moet worden naar de laagst mogelijke dosering. Stop in ieder geval nooit met uw reuma medicatie zonder overleg met uw arts.	The use of rheumatism medication such as methotrexate and biologicals can, because of the mechanism of action of these medicines, cause a reduced resistance to infections. There are no data available to COVID-19 available yet. If you are not ill, there is no reason to stop your rheumatism medication, this could actually increase your risk of a rheumatism flare. The advice is to continue to use the medication, in which we should always follow to us the lowest possible dose. In any case, do not stop with your rheumatism medication without consulting your physician.

Legend:      Simple sentences;      Long sentences;      Passive sentences;      Complex sentences;      Long paragraphs

**Figure 1.** Example of textual assessment using the application. Note: Dutch-language text was used for analysis; the English translation is provided as a reference only and might be of different difficulty.

**Results:** While admittedly being underprepared, respondents generally perceived their crisis communication as adequate. They quickly adapted to people's needs and changing circumstances and attempted to adapt written and verbal communication to people with limited health literacy. Respondents reported challenges related to the scientific uncertainty, lack of reach, difficulty simplifying information, and being unsure if their communication approach was adequate. Textual assessment showed great variation in applicability (range 60-100%) and comprehensibility (range 58-100%) of these texts, and 69% of communications were more difficult than B1-level. Considering principles of crisis communication and health literacy, we propose several lessons to be learned for future crises (Table 1).

#### Table 1. Recommendations for improvement of crisis communication

##### Preparedness:

Use current experience to establish a future crisis communication plan  
Train staff and management in crisis communication and health literate communication

##### Strategy:

Collaborate with relevant organisations to ensure consistency in messages  
Inform people early and frequently  
Remain transparent about uncertainty

##### Content:

Adapt information to different people's needs, considering e.g. age, cultural background  
Check difficulty level of written information (aim at B1) and adapt accordingly  
Ask your audience for feedback  
Make sure information is directly applicable in practice  
Combat fake news through acknowledgement and counterarguments

##### Reach:

Use multiple channels  
Use diverse outreach strategies to cater to a diverse audience

##### Overall:

Consider people's health literacy throughout

**Conclusion:** The rheumatology organisations mostly adhered to principles of crisis communication, and made efforts to adapt information to their audience's needs, including health literacy needs. Nevertheless, important recommendations were drawn which are potentially also relevant for other clinical fields.

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### LB0001 MAVRILIMUMAB IMPROVES OUTCOMES IN PHASE 2 TRIAL IN NON-MECHANICALLY-VENTILATED PATIENTS WITH SEVERE COVID-19 PNEUMONIA AND SYSTEMIC HYPERINFLAMMATION

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**Background:** Granulocyte/macrophage-colony stimulating factor (GM-CSF) is a cytokine both vital to lung homeostasis and important in regulating inflammation and autoimmunity<sup>1,2,3</sup> that has been implicated in the pathogenesis of respiratory failure and death in patients with severe COVID-19 pneumonia and systemic hyperinflammation.<sup>4-6</sup> Mavrilimumab is a human anti GM-CSF receptor  $\alpha$  monoclonal antibody capable of blocking GM-CSF signaling and downregulating the inflammatory process.

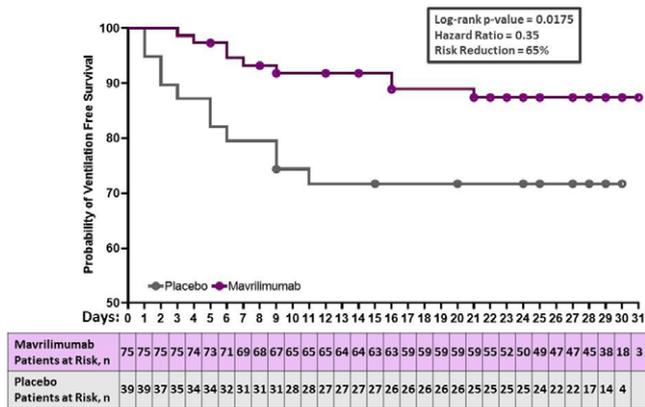
**Objectives:** To evaluate the effect of mavrilimumab on clinical outcomes in patients hospitalized with severe COVID-19 pneumonia and systemic hyperinflammation.

**Methods:** This on-going, global, randomized, double-blind, placebo-controlled seamless transition Phase 2/3 trial was designed to evaluate the efficacy and safety of mavrilimumab in adults hospitalized with severe COVID-19 pneumonia and hyperinflammation. The Phase 2 portion comprised two groups: Cohort 1 patients requiring supplemental oxygen therapy without mechanical

ventilation (to maintain SpO<sub>2</sub> ≥92%) and Cohort 2 patients requiring mechanical ventilation, initiated ≤48 hours before randomization. Here, we report results for Phase 2, Cohort 1: 116 patients with severe COVID-19 pneumonia and hyperinflammation from USA, Brazil, Chile, Peru, and South Africa; randomized 1:1 to receive a single intravenous administration of mavrilimumab (10 or 6 mg/kg) or placebo. The primary efficacy endpoint was proportion of patients alive and free of mechanical ventilation at Day 29. Secondary endpoints included [1] time to 2-point clinical improvement (National Institute of Allergy and Infectious Diseases COVID-19 ordinal scale), [2] time to return to room air, and [3] mortality, all measured through Day 29. The prespecified evidentiary standard was a 2-sided α of 0.2 (not adjusted for multiplicity).

**Results:** Baseline demographics were balanced among the intervention groups; patients were racially diverse (43% non-white), had a mean age of 57 years, and 49% were obese (BMI ≥ 30). All patients received the local standard of care: 96% received corticosteroids (including dexamethasone) and 29% received remdesivir. No differences in outcomes were observed between the 10mg/kg and 6mg/kg mavrilimumab arms. Results for these groups are presented together. Mavrilimumab recipients had a reduced requirement for mechanical ventilation and improved survival: at day 29, the proportion of patients alive and free of mechanical ventilation was 12.3 percentage points higher with mavrilimumab (86.7% of patients) than placebo (74.4% of patients) (Primary endpoint; p=0.1224). Mavrilimumab recipients experienced a 65% reduction in the risk of mechanical ventilation or death through Day 29 (Hazard Ratio (HR) = 0.35; p=0.0175). Day 29 mortality was 12.5 percentage points lower in mavrilimumab recipients (8%) compared to placebo (20.5%) (p=0.0718). Mavrilimumab recipients had a 61% reduction in the risk of death through Day 29 (HR= 0.39; p=0.0726). Adverse events occurred less frequently in mavrilimumab recipients compared to placebo, including secondary infections and thrombotic events (known complications of COVID-19). Thrombotic events occurred only in the placebo arm (5/40 [12.5%]).

**Mavrilimumab Reduced the Risk of Mechanical Ventilation or Death by 65% Versus Placebo**



**Conclusion:** In a global, diverse population of patients with severe COVID-19 pneumonia and hyperinflammation receiving supplemental oxygen therapy, corticosteroids, and remdesivir, a single infusion of mavrilimumab reduced progression to mechanical ventilation and improved survival. Results indicate mavrilimumab, a potent inhibitor of GM-CSF signaling, may have added clinical benefit on top of the current standard therapy for COVID-19. Of potential importance is that this treatment strategy is mechanically independent of the specific virus or viral variant.

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**LB0002 COVID-19 VACCINE SAFETY IN PATIENTS WITH RHEUMATIC AND MUSCULOSKELETAL DISEASE**

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**Background:** The consequences of the COVID-19 outbreak are unprecedented and have been felt by everyone around the world, including people with rheumatic and musculoskeletal diseases (RMDs). With the development of vaccines, the future is becoming brighter. Vaccines are a key pillar of public health and have been proven to prevent many serious diseases. However, vaccination also raises questions, especially for patients with inflammatory RMDs and/or treated with drugs that influence their immune system.

**Objectives:** Our aim was to collect safety data among RMD patients receiving COVID-19 vaccines.

**Methods:** The EULAR COVID-19 Vaccination (COVAX) Registry is an observational registry launched on 5 February 2021. Data are entered voluntarily by clinicians or associated healthcare staff; patients are eligible for inclusion if they have an RMD and have been vaccinated against SARS-CoV-2. Descriptive statistics are presented.

**Results:** As of 27 April 2021, 1519 patients were reported to the registry. The majority were female (68%) and above the age of 60 (57%). Mean age was 63 years (SD 16), ranging from 15 to 97 years. A total of 28 countries contributed to the registry, with France (60%) and Italy (13%) as the highest contributors. The majority (91%) had inflammatory RMDs. Inflammatory joint diseases accounted for 51% of cases, connective tissue diseases 19%, vasculitis 16%, other immune mediated inflammatory diseases 4%, and non-inflammatory/mechanical RMDs 9%. The most frequent individual diagnoses were rheumatoid arthritis (30%), axial spondyloarthritis (8%), psoriatic arthritis (8%), systemic lupus erythematosus (SLE, 7%) and polymyalgia rheumatica (6%). At the time of vaccination, 45% were taking conventional synthetic DMARDs, 36% biological DMARDs, 31% systemic glucocorticoids, 6% other immunosuppressants (azathioprine; mycophenolate; cyclosporine; cyclophosphamide; tacrolimus), and 3% targeted synthetic DMARDs. The most frequent individual DMARDs were methotrexate (29%), TNF-inhibitors (18%), antimalarials (10%) and rituximab (6%). The vaccines administered were: 78% Pfizer, 16% AstraZeneca, 5% Moderna and 1% other/unknown; 66% of cases received two doses and 34% one dose. Mean time from 1st and 2nd dose to case report was 41 days (SD 26) and 26 days (SD 23), respectively. COVID-19 diagnosis after vaccination was reported in 1% (18/1519) of cases. Mean time from first vaccination until COVID-19 diagnosis was 24 days (SD 17). Disease flares were reported by 5% (73/1375) of patients with inflammatory RMDs, with 1.2% (17/1375) classified as severe flares. Mean time from closest vaccination date to inflammatory RMD flare was 5 days (SD 5). The most common flare types were arthritis (35/1375=2.5%), arthralgia (29/1375=2.1%), cutaneous flare (11/1375=0.8%) and increase in fatigue (11/1375=0.8%). Potential vaccine side effects were reported by 31% of patients (467/1519). The majority were typical early adverse events within 7 days of vaccination, namely pain at the site of injection (281/1519=19%), fatigue (171/1519=11%) and headache (103/1519=7%). Organ/system adverse events were reported by 2% (33/1519) but only 0.1% (2/1519) reported