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REVIEW

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Acute and chronic inflammatory neuropathies and COVID-19 vaccines: Practical recommendations from the task force of the Italian Peripheral Nervous System Association (ASNP)

Pietro E. Doneddu[1] | Emanuele Spina[2] | Chiara Briani[3] | Gian Maria Fabrizi[4] | Fiore Manganelli[2] | Eduardo Nobile-Orazio[1,5] | the Italian Peripheral Nervous System Association (ASNP)

[1]Neuromuscular and Neuroimmunology Service, IRCCS Humanitas Research Hospital, Milan, Italy

[2]Department of Neuroscience, Reproductive Sciences and Odontostomatology, University of Naples "Federico II", Naples, Italy

[3]Neurology Unit, Department of Neuroscience, University of Padova, Padova, Italy

[4]Neurology Unit, Department of Neuroscienze, University of Verona, Policlinico Hospital G.B. Rossi, Verona, Italy

[5]Department of Medical Biotechnology and Translational Medicine, Milan University, Milan, Italy

Correspondence
Eduardo Nobile-Orazio, MD, PhD, FAAN, FEAN, Neuromuscular and Neuroimmunology Service, IRCCS Humanitas Research Hospital, Via Manzoni 56, Rozzano, Milan 20089, Italy.
Email: eduardo.nobile@unimi.it

Abstract

Background and aims: To develop recommendations for vaccination for coronavirus-19 (COVID-19) in patients with inflammatory neuropathies.

Methods: Key questions were formulated in order to perform a literature review on the safety and efficacy of vaccines in patients with inflammatory neuropathies. Based on the best evidence and expert opinion, a list of recommendations was formulated to inform decision on vaccination for COVID-19 in patients with inflammatory neuropathies and increase adherence to vaccination programmes.

Results: Recommendations addressing safety and efficacy of vaccination in patients with inflammatory neuropathies were formulated. No data are currently available on the safety and efficacy of COVID-19 vaccines in patients with inflammatory neuropathies or other immune-mediated conditions. There is only sparse data on the safety of previous available vaccines in patients with inflammatory neuropathies, but studies on other autoimmune disorders indicate that these are safe and mostly efficacious. Patients with inflammatory neuropathies might be at increased risk for severe illness from COVID-19.

Interpretation: Patients with inflammatory neuropathies should be encouraged to adhere to the vaccination campaign for COVID-19. These recommendations provide guidance on the management of vaccinations for COVID-19 in patients with inflammatory neuropathies. More research is needed regarding the safety and efficacy of vaccination in patients with inflammatory neuropathies and other immune conditions.

KEYWORDS
coronavirus disease, COVID-19, inflammatory neuropathies, vaccination, vaccine

1 | INTRODUCTION

The global vaccination campaign in response to the coronavirus-19 (COVID-19) pandemic has started with an unprecedented speed. Considering the severity of the pandemic, a massive effort has been made internationally to shorten the timing of vaccine development and dissemination in order to guarantee adequate protection against the risk of getting COVID-19 disease. Given the high-efficacy observed, it was not possible, for ethical reasons, to evaluate the long-term efficacy and safety of the vaccines for COVID-19 in comparison to a placebo group.[1] The occasional association of vaccines with the onset of inflammatory

Pietro E. Doneddu, Emanuele Spina, Eduardo Nobile-Orazio, and Fiore Manganelli equally contributed to the article.

neuropathies together with the sparse information on the safety and efficacy of the vaccines for COVID-19 in people with autoimmune diseases raised some concerns about safety in patients with immune-mediated neuropathies. The Italian Association of the Peripheral Nervous System (ASNP) has developed a joint document to provide the neurological community and patients with the best evidence for informing decision on vaccination for COVID-19 in patients with immune-mediated neuropathies and increase adherence to vaccination programmes. The following document should be interpreted as a collection of indications or advice developed by neurologists with expertise in immune-mediated polyneuropathies (ie, Guillain-Barré syndrome [GBS] and its variants; chronic inflammatory demyelinating polyradiculoneuropathy [CIDP], multifocal motor neuropathy [MMN], polyneuropathies associated with monoclonal gammopathy with or without anti-MAG antibodies and vasculitic neuropathies).

2 | ARE VACCINES A RISK FACTOR FOR THE DEVELOPMENT OF INFLAMMATORY NEUROPATHIES?

The possible association between vaccines and inflammatory neuropathies has been a matter of concern since the year 1976, when a vaccination campaign was interrupted in the U.S. due to an increased number of GBS cases after receiving the swine influenza vaccine.[2] Since then, a number of studies addressed the possible association of vaccines with GBS.[3-7] These epidemiological studies gave mixed results, with the majority of them failing to show evidence of the association of GBS with vaccines.[8,9] However, these studies were underpowered to detect a small relative risk.[8-10] A few studies on a larger number of patients and meta-analyses reported a small but significant increased risk of GBS after influenza vaccine (1 additional case of GBS per million persons vaccinated).[10-16] In an attempt to determine the presence of any possible confounding factor due to the simultaneous circulation of wild-type influenza virus (a known risk factor of GBS)[17,18] and influenza vaccine, one study evaluated the cumulative risk of GBS in the vaccinated and unvaccinated population.[19] The cumulative risk of GBS was significantly higher among the unvaccinated population than in the vaccinated population.[19] The lesson we can learn from these studies is that an increased risk of GBS has been found to be associated with both influenza infections and some influenza vaccines; however, the slightly increased risk of GBS following vaccination should be weighed against the potential benefits of vaccination against influenza and against the much higher risk of GBS caused by influenza virus infection.

Apart from GBS, only a few studies have evaluated the association between vaccines and chronic inflammatory neuropathies.[20-22] A proportion of CIDP patients ranging from 1.5% to 11% report a preceding vaccination within 8 weeks from the onset of the first neuropathy symptoms.[20,22] Limitations of these studies include the retrospective design, the risk of recall bias, and the difficulty of accurately dating the onset of chronic disorders. There are also isolated reports on vasculitic neuropathies following vaccination.[23,24] However, higher quality studies and a systematic review found no causal association between vaccination and subsequent development of vasculitis.[25-27] No studies have investigated vaccination as a risk factor for MMN and anti-MAG antibody neuropathy.

3 | ARE VACCINES SAFE AND EFFICACIOUS IN PEOPLE WITH INFLAMMATORY NEUROPATHIES?

Another matter of concern is the putative risk of relapse following vaccination in patients with immune-mediated neuropathies. Only two retrospective studies have investigated this issue in GBS and CIDP, while no studies focused on MMN or anti-MAG antibody neuropathy.[20,21] One study found that 11/311 (3.5%) previously diagnosed GBS patients and 5/65 (8%) CIDP patients reported worsening of neurological symptoms after immunization.[21] Only one of the GBS patients however experienced transient worsening of disability and only one of the CIDP patients required treatment while in all other patients symptoms were self-reported, mild, and resolved spontaneously. In another study, 0/106 GBS patients and 5/24 (21%) CIDP patients reported an increase in symptoms after one or more vaccinations.[20] It is difficult to draw firm conclusions from these studies given their small sample size and the retrospective design. Keeping these limitations in mind, these studies suggest a low risk of worsening of GBS and CIDP after vaccines. Two retrospective studies and two randomized controlled trials confirmed safety of influenza vaccine in anti-neutrophil cytoplasmic antibody associated vasculitis.[26,28-30] Unfortunately, the proportion of patients with peripheral neuropathy among those included in these studies is not reported. No studies have evaluated the efficacy of vaccination in patients with inflammatory neuropathies.

4 | WHAT IS THE EVIDENCE ON THE SAFETY AND EFFICACY OF VACCINATION IN AUTOIMMUNE DISEASES?

High quality studies conducted on patients with different autoimmune disorders, such as vasculitis,[28,29] lupus erythematosus,[31] rheumatoid arthritis,[31-35] multiple sclerosis,[36,37] myasthenia gravis,[38,39] or diabetes mellitus,[40] showed that vaccination is safe and it is not associated with an increased risk of relapse. Most of the studies demonstrated similar rates of immunogenicity among patients with autoimmune disorders and healthy subjects.[26,28-40] No data are currently available on the safety and efficacy of COVID-19 vaccines in people with autoimmune diseases.

5 | IS VACCINATION SAFE AND EFFICACIOUS FOR PEOPLE WITH INFLAMMATORY NEUROPATHY UNDER IMMUNE-MODULATING OR IMMUNE-SUPPRESSIVE THERAPY?

Only a minority of patients with CIDP are immunosuppressed. According to the data of the Italian CIDP database, the percentage of patients with

CIDP under immunosuppressive treatment, excluding those receiving intravenous immunoglobulin (IVIg) or corticosteroids or plasma exchange (see below) is 16%.[41] This percentage is much lower in patients with MMN, whereas it reaches 86% in patients with anti-MAG antibody neuropathy.[42] There is no data in literature on the safety of vaccination in patients with inflammatory neuropathy under immunosuppressive treatment. There are however several studies that assessed safety and immunogenicity of vaccination in patients with different autoimmune disorders under immunosuppressive treatment. These studies showed that non-live vaccines are safe in the setting of immunosuppression, and that immunosuppressive therapies have a variable impact on the response to immunization with vaccines, with the majority of patients reaching a satisfactory serological response, although usually reduced compared to immunocompetent people.[43-48] Rituximab profoundly reduces vaccine immunogenicity.[35,49] The evidence coming from these studies suggest that, to ensure the best chance of response, whenever possible immunization should be administered prior to initiation of immunosuppressive medications.[35,43-49] Live vaccines are contraindicated in immunosuppressed patients.[43-48] None of the approved COVID-19 vaccines however contain any active severe acute respiratory syndrome coronavirus-2 (SARS-CoV-2) virus.

6 | IS VACCINATION SAFE AND EFFICACIOUS IN PEOPLE WITH INFLAMMATORY NEUROPATHY UNDER TREATMENT WITH INTRAVENOUS IMMUNOGLOBULIN OR SUBCUTANEOUS IMMUNOGLOBULIN?

Antibodies to COVID-19 may not be found yet in therapeutic IVIg or subcutaneous immunoglobulin (SCIg), thus patients under treatment with these therapies are not protected against COVID-19. Since there is the potential risk of a reduced effectiveness of the COVID-19 vaccines if IVIg are administered with, or shortly before or after the vaccine, some authors[50] and some national guidelines on immunization[51-53] recommend vaccination more than 2 weeks before the cycle of IVIg or at least 8 weeks after. This would be quite difficult in patients with chronic immune-mediated neuropathies in whom IVIg need to be periodically administered every 2 to 5 weeks to avoid clinical deterioration. Administration of SCIg can also reduce the efficacy of vaccines for a similar period.[54,55] There are no additional safety concerns if IVIg or SCIg are administered with, or shortly before or after the vaccine. It is however recommendable to prefer another site of injection for COVID-19 vaccine respect to those usually used to administer SCIg.

7 | IS VACCINATION SAFE AND EFFICACIOUS IN PEOPLE WITH INFLAMMATORY NEUROPATHY UNDER TREATMENT WITH CORTICOSTEROIDS?

The amount of systemically absorbed corticosteroids and the duration of administration needed to suppress the immune system of an otherwise immunocompetent person are not well defined. A dose equivalent to either ≥2 mg/kg of body weight or ≥ 20 mg/day of prednisone or equivalent for people who weigh >10 kg when administered for ≥14 consecutive days is considered as sufficiently immunosuppressive to raise concern about the safety of vaccination with live-virus vaccines.[56] In patients initiating steroid therapy, it is recommended to start treatment at least 4 weeks after live vaccines and 2 weeks after inactivated vaccines.[56] In patients under chronic steroid therapy the main risk would be however a reduced efficacy of the vaccines.

8 | IS VACCINATION SAFE AND EFFICACIOUS IN PEOPLE WITH INFLAMMATORY NEUROPATHY UNDER TREATMENT WITH PLASMA EXCHANGE?

Some studies suggest that antibody titers correlated with protection to diphtheria, Epstein-Barr virus, and tetanus remained above thresholds associated with protection for most patients after plasma exchange.[57] Other studies showed that antibodies against pneumococcus, haemophilus polysaccharide, and measles antigens were significantly reduced, in some patients even below the protective threshold values.[58-60] The effect of chronically administered plasma exchange on the levels of protective antibodies is uncertain.[61] The evidence coming from these studies suggest that, to ensure the best chance of response, immunization should be administered prior to initiation of plasma exchange whenever possible.

9 | COVID-19 VACCINES

Since January 2020, 172 and 63 vaccines are in pre-clinical and clinical development, respectively; 21 of them are in experimental stage 3 or late 2/early 3.[62] Virtually all possible kind of vaccines are in the pipeline to prevent COVID-19, from whole virion SARS-CoV-2 vaccines (inactivated and live attenuated) to those based on spike (S) protein (replicating or non-replicating viral vectored vaccine, recombinant protein vaccine, virus like particles vaccine, peptide based vaccine, DNA/RNA vaccine, plant based vaccine).[63] To develop useful vaccines the main target is the S protein, because spike-specific antibodies can interfere with interaction between SARS-CoV-2 virus and human cells, preventing the infection.

Currently the European Medicines Agency (EMA) has granted for European Unit (EU) conditional marketing authorisation for two mRNA vaccines, Pfizer for ages ≥16 years, and Moderna for ≥18 years while the AstraZeneca vaccine, in which chimpanzee-adenoviral vector contains the SARS-CoV-2 structural surface glycoprotein antigen gene, has been just recently approved for adults ≥18 years.[1,64-66]

There are three more vaccines on EMA rolling review (the step before conditional marketing authorisation): Ad26.COV2.S (developer: Janssen-Cilag International N.V.), an adenovirus vectored vaccine;

NVX-CoV2373 (by Novavax CZ AS), a full-length recombinant SARS-CoV-2 glycoprotein nanoparticle vaccine adjuvanted with Matrix M and CVnCoV (by CureVac AG), a mRNA vaccine similar to Pfizer and Moderna vaccines.[67]

All these vaccines are classified as non-replicating vaccines. In mRNA vaccines, the mRNA molecules are included in lipid nanoparticles that allow the fusion with cellular membranes of host cells and hence the mRNA is released in the cytoplasm, where it is translated to build the spike protein. The spike protein has two punctiform mutations, to get the best structural conformation for antigenic behavior, inducing both humoral and cellular immune response against SARS-CoV-2 infection. The mRNA vaccines do not contain the entire viral genetic information, lacking M, N, and E proteins and other subgenomic RNAs, so it is impossible any replication or integration in the host DNA.[1,66,67] The Janssen-Cilag and AstraZeneca vaccines are DNA-based COVID-19 vaccines. In AstraZeneca vaccine, the gene for the coronavirus spike protein is added to a modified version of a chimpanzee adenovirus that can enter cells, but it cannot replicate inside them; in the Janssen-Cilag vaccine, the gene for the coronavirus spike protein is added to a replication-incompetent human recombinant adenovirus vector (AD26). Anyway, the gene for the SARS-CoV-2 spike protein can be read by the cell and copied into mRNA and ultimately translated to build spike protein. Protruding spikes or spike fragments are presented on the surface of infected cells and can be recognized by the immune system, developing neutralizing antibodies.[68,69]

NVX-CoV2373 is a nanoparticle-based vaccine, containing viral proteins without the accompanying genetic material. NVX-CoV2373 consists of a recombinant SARS-CoV-2 constructed from the full-length wild-type SARS-CoV-2 spike glycoprotein with resistance to protease and a M1 saponin-based adjuvant. It has demonstrated high immunogenicity and an acceptable safety.[70]

Among vaccines being administered out of EU and not yet on EMA review we must cite "Sputnik V", (rAd26-S + rAd5-S-Gamaleya National Research Centre, Russia), the first vaccine to be approved for preventing COVID-19. This vaccine is a non-replicating vaccine consisting on two recombinant components, both based on human adenovirus containing S-protein gene.[71]

10 | ARE THE VACCINES FOR COVID-19 EFFICACIOUS AND SAFE IN PATIENTS WITH INFLAMMATORY NEUROPATHIES?

People with an immunocompromised condition or treated with immunosuppressive therapy were excluded from participation in the COVID-19 vaccine trials, and thus there is no information on safety and response after immunization in these patients.[1,65,72,73] The Center for Disease Control and Prevention (CDC) and, in Italy, the National Federation Drug (Agenzia Italiana del Farmaco-AIFA), have published their recommendations where it is stated that people with autoimmune conditions or under medication with immunosuppressive agents may receive a COVID-19 vaccine although they should be aware of the limited safety data.[74,75] A multicentre Italian prospective study designed to evaluate the risk of relapse after vaccination and the safety of COVID-19 vaccines in patients with chronic inflammatory neuropathies is ongoing.

11 | WHAT ARE THE RISKS OF GETTING COVID-19?

Estimated worldwide mortality of COVID-19 is about 0.3/1000 persons,[76] but the data of western countries tend to have higher numbers.[77] In Italy mortality of COVID-19 is 1.5/1000, with a case fatality ratio of 3.5% and an average intensive care unit (ICU) admission rate of 21.4%.[77,78] Currently, there are limited data and information about the impact of many underlying medical conditions on the risk for severe illness from COVID-19. Based on what we know at this time, the CDC includes neurologic conditions and an immunocompromised state from the use of corticosteroids or other immune weakening medicines as two independent conditions that might be at increased risk for severe illness from COVID-19.[79]

12 | RECOMMENDATIONS

- The vaccination programme for COVID-19 should be explained to the patients with inflammatory neuropathies providing a basis for shared decision-making. The patients should be informed that no data are currently available on the safety and efficacy of COVID-19 vaccines in people with autoimmune and immune-mediated conditions. However, evidence coming from previous vaccines suggest that patients who had GBS in the past, patients with chronic inflammatory neuropathy and those with an autoimmune disorder do not have an increased risk of relapse following vaccination, thus they should be encouraged to adhere to the vaccination campaign for COVID-19.

- Vaccination for COVID-19 in patients with chronic inflammatory neuropathy should preferably be administered during a remission phase of the disease. The rationale for this recommendation is that most vaccination studies conducted in people with autoimmune disorders included patients with disease in remission. Clinicians should delay vaccination of people with chronic inflammatory neuropathy who are experiencing a relapse until clinical resolution or until the relapse is no longer active.

- Until further data comes from vaccine surveillance for COVID-19 under real-life conditions, patients who had GBS in the past or with chronic inflammatory neuropathy who decide to get vaccinated should continue to follow all local current guidance to protect themselves against COVID-19 after they are vaccinated.

- Vaccination for COVID-19 should be administered at least 2 weeks prior to initiation of steroid therapy whenever possible. In patients with chronic inflammatory neuropathy requiring steroid therapy it is not recommended to delay or interrupt treatment for vaccination. In patients under long-term steroid therapy in immunosuppressive regimen it is recommended to monitor seroconversion with antibody testing

2 weeks after the second dose of vaccine. Monthly intravenous bolus of methylprednisolone is not considered an immunosuppressive treatment, so vaccines could be administered 2 weeks after the therapy.

- Vaccination for COVID-19 should be administered at least 2 weeks prior to initiation of IVIg or SCIg therapy whenever possible. In patients with chronic inflammatory neuropathy requiring IVIg or SCIg therapy it is not recommended to delay or interrupt treatment for vaccination. In patients under IVIg treatment, vaccination should be administered at least 2 weeks before or 8 weeks after the infusion of IVIg whenever possible. If not possible, vaccines should preferably be administered in the middle of two cycles. Monitoring of serologic conversion 2 weeks after the second dose of vaccine is advisable in patients under IVIg or SCIg treatment. In patients treated with SCIg, it is recommendable to choose a site of injection for COVID-19 vaccine different from that usually used for SCIg.

- Vaccination for COVID-19 should be administered at least 2 weeks prior to initiation of methotrexate, azathioprine, mycophenolate mofetil or cyclophosphamide therapy whenever possible. In patients with chronic inflammatory neuropathy requiring treatment with the above-mentioned drugs it is not recommended to delay or interrupt treatment for vaccination. In patients under treatment with intravenous cyclophosphamide, the two doses of COVID-19 vaccine should be administered between two infusions. Monitoring of serologic conversion 2 weeks after the second dose of vaccine is advisable in these patients.

- A suboptimal efficacy of the vaccine for COVID-19 in patients under treatment with rituximab is possible. In patients with chronic inflammatory neuropathy requiring treatment with rituximab it is not recommended to delay or interrupt treatment for vaccination. Monitoring of serologic conversion 2 weeks after the second dose of vaccine is advisable in these patients.

- Regarding COVID-19 vaccines administered in two doses, the protective effect of immunization vaccination reaches full efficacy one or two weeks after the second dose.

- The possibility of a third vaccine booster dose could theoretically be considered in patients under immunosuppressive therapy that do not exhibit serologic conversion, even if this has not been yet considered by regulatory agencies.

In conclusion, evidence from previous vaccines in people with inflammatory neuropathies or autoimmune disorders suggests that vaccination in these groups of patients is safe and effective in most cases. The safety and efficacy of vaccination in patients under treatment with immune-modulating or immune-suppressive therapies need however to be further evaluated. We provide recommendations to guide physicians in the use of vaccination for COVID-19 and encourage our patients to join vaccination programmes.

AUTHORS CONTRIBUTIONS

Pietro E. Doneddu and Emanuela Spina, screened the articles, assessed quality, extracted data, analyzed the data, and wrote the first draft of the article. Fiore Manganelli and Eduardo Nobile-Orazio, conceptualized the article, reviewed and revised the article for intellectual content. Chiara Briani and Gian Maria Fabrizi, reviewed and revised the article for intellectual content. All authors read and approved the final version of the article.

DATA AVAILABILITY STATEMENT

Data are available on request from the corresponding author.

ORCID

Pietro E. Doneddu https://orcid.org/0000-0003-4203-6792
Chiara Briani https://orcid.org/0000-0001-8035-0200
Gian Maria Fabrizi https://orcid.org/0000-0001-6804-0226
Fiore Manganelli https://orcid.org/0000-0001-9478-3744
Eduardo Nobile-Orazio https://orcid.org/0000-0003-2624-8138

REFERENCES

1. Polack FP, Thomas SJ, Kitchin N, et al. Safety and efficacy of the BNT162b2 mRNA Covid-19 vaccine. *N Engl J Med*. 2020;383(27):2603-2615.
2. Schonberger LB, Bregman DJ, Sullivan-Bolyai JZ, et al. Guillain-Barré syndrome following vaccination in the National Influenza Immunization Program, United States, 1976–1977. *Am J Epidemiol*. 1979;110(2):105-123.
3. Tay SY, Chan WP. A 9-year-old female with bilateral leg weakness after influenza vaccination. *Pediatr Ann*. 2014;43(11):440-441.
4. Remiche G, Abramowicz M, Mavroudakis N. Chronic inflammatory demyelinating polyradiculoneuropathy (CIDP) associated to hereditary neuropathy with liability to pressure palsies (HNPP) and revealed after influenza AH1N1 vaccination. *Acta Neurol Belg*. 2013;113(4):519-522.
5. Gable KL, Afshari Z, Sufit RL, Allen JA. Distal acquired demyelinating symmetric neuropathy after vaccination. *J Clin Neuromuscul Dis*. 2013;14(3):117-122.
6. Latov N, Wu AT, Chin RL, Sander HW, Alaedini A, Brannagan TH 3rd. Neuropathy and cognitive impairment following vaccination with the OspA protein of Borrelia burgdorferi. *J Peripher Nerv Syst*. 2004;9(3):165-167.
7. Brostoff JM, Beitverda Y, Birns J. Post-influenza vaccine chronic inflammatory demyelinating polyneuropathy. *Age Ageing*. 2008;37(2):229-230.
8. Salmon DA, Dudley MZ, Carleton BC. Guillain-Barré syndrome following influenza vaccines affords opportunity to improve vaccine confidence. *J Infect Dis*. 2020;2:jiaa544.
9. Vellozzi C, Iqbal S, Broder K. Guillain-Barre syndrome, influenza, and influenza vaccination: the epidemiologic evidence. *Clin Infect Dis*. 2014;58(8):1149-1155.
10. Martín Arias LH, Sanz R, Sáinz M, Treceño C, Carvajal A. Guillain-Barré syndrome and influenza vaccines: a meta-analysis. *Vaccine*. 2015;33(31):3773-3778.
11. Juurlink DN, Stukel TA, Kwong J, et al. Guillain-Barre syndrome after influenza vaccination in adults—a population-based study. *Arch Int Med*. 2006;166(20):2217-2221.
12. Lasky T, Terracciano GJ, Magder L, et al. The Guillain-Barre syndrome and the 1993 and 1993–1994 influenza vaccines. *N Engl J Med*. 1998;339(25):1797-1802.
13. Fiore AE, Uyeki TM, Broder K, et al. Prevention and control of influenza with vaccines: recommendations of the advisory committee on immunization practices (ACIP), 2010. *MMWR Recomm Rep*. 2010;59(RR-8):1-62.
14. Centers for Disease Control and Prevention (CDC). Preliminary results: surveillance for Guillain-Barré syndrome after receipt of influenza a (H1N1) 2009 monovalent vaccine - United States, 2009–2010. *MMWR Morb Mortal Wkly Rep*. 2010;59(21):657-661.
15. Tokars JI, Lewis P, DeStefano F, et al. The risk of Guillain-Barre syndrome associated with influenza a (H1N1) 2009 monovalent vaccine

and 2009–2010 seasonal influenza vaccines: results from self-controlled analyses. *Pharmacoepidemiol Drug Saf*. 2012;21(5):546-552.
16. Wise ME, Viray M, Sejvar JJ, et al. Guillain-Barre syndrome during the 2009–2010 H1N1 influenza vaccination campaign: population-based surveillance among 45 million Americans. *Am J Epidemiol*. 2012;175(11):1110-1119.
17. Stowe J, Andrews N, Wise L, Miller E. Investigation of the temporal association of Guillain-Barre syndrome with influenza vaccine and influenza like illness using the United Kingdom general practice research database. *Am J Epidemiol*. 2009;169(3):382-388.
18. Tam CC, O'Brien SJ, Petersen I, Islam A, Hayward A, Rodrigues LC. Guillain-Barre syndrome and preceding infection with campylobacter, influenza and Epstein-Barr virus in the general practice research database. *PLoS One*. 2007;2(4):e344.
19. Vellozzi C, Iqbal S, Stewart B, Tokars J, DeStefano F. Cumulative risk of Guillain-Barré syndrome among vaccinated and unvaccinated populations during the 2009 H1N1 influenza pandemic. *Am J Public Health*. 2014;104(4):696-701.
20. Kuitwaard K, Bos-Eyssen ME, Blomkwist-Markens PH, van Doorn PA. Recurrences, vaccinations and long-term symptoms in GBS and CIDP. *J Peripher Nerv Syst*. 2009;14(4):310-315.
21. Pritchard J, Mukherjee R, Hughes RA. Risk of relapse of Guillain–Barre´ syndrome or chronic inflammatory demyelinating polyradiculoneuropathy following immunization. *J Neurol Neurosurg Psychiatry*. 2002;73(3):343-350.
22. Doneddu PE, Bianchi E, Cocito D, et al. Risk factors for chronic inflammatory demyelinating polyradiculoneuropathy (CIDP): antecedent events, lifestyle and dietary habits. Data from the Italian CIDP database. *Eur J Neurol*. 2020;27(1):136-143.
23. Watanabe T. Vasculitis following influenza vaccination: a review of the literature. *Curr Rheumatol Rev*. 2017;13(3):188-196.
24. Muñiz AE. Lymphocytic vasculitis associated with the anthrax vaccine: case report and review of anthrax vaccination. *J Emerg Med*. 2003;25(3):271-276.
25. Abrams JY, Weintraub ES, Baggs JM, et al. Childhood vaccines and Kawasaki disease, vaccine safety Datalink, 1996-2006. *Vaccine*. 2015;33(2):382-387.
26. Stassen PM, Sanders JS, Kallenberg CG, Stegeman CA. Influenza vaccination does not result in an increase in relapses in patients with ANCA-associated vasculitis. *Nephrol Dial Transplant*. 2008;23(2):654-658.
27. Bonetto C, Trotta F, Felicetti P, et al. Vasculitis as an adverse event following immunization - systematic literature review. *Vaccine*. 2016;34(51):6641-6651.
28. Jeffs LS, Peh CA, Jose MD, Lange K, Hurtado PR. Randomized trial investigating the safety and efficacy of influenza vaccination in patients with antineutrophil cytoplasmic antibody-associated vasculitis. *Nephrology (Carlton)*. 2015;20(5):343-351.
29. Holvast A, Stegeman CA, Benne CA, et al. Wegener's granulomatosis patients show an adequate antibody response to influenza vaccination. *Ann Rheum Dis*. 2009;68(6):873-878.
30. Zycinska K, Romanowska M, Nowak I, Rybicka K, Wardyn KA, Brydak LB. Antibody response to inactivated subunit influenza vaccine in patients with Wegener's granulomatosis. *J Physiol Pharmacol*. 2007;58(suppl 5 (Pt 2)):819-828.
31. Del Porto F, Laganà B, Biselli R, et al. Influenza vaccine administration in patients with systemic lupus erythematosus and rheumatoid arthritis. *Safety Immunog Vaccine*. 2006;24(16):3217-3223.
32. Colmegna I, Useche ML, Rodriguez K, et al. Immunogenicity and safety of high-dose versus standard-dose inactivated influenza vaccine in rheumatoid arthritis patients: a randomised, double-blind, active-comparator trial. *The Lancet Rheumatol*. 2020;2:e14-e23.
33. Chalmers A, Scheifele D, Patterson C, et al. Immunization of patients with rheumatoid arthritis against influenza: a study of vaccine safety and immunogenicity. *J Rheumatol*. 1994;21(7):1203-1206.
34. Fomin I, Caspi D, Levy V, et al. Vaccination against influenza in rheumatoid arthritis: the effect of disease modifying drugs, including TNFα blockers. *Ann Rheum Dis*. 2006;65(2):191-194.
35. van Assen S, Holvast A, Benne CA, et al. Humoral responses after influenza vaccination are severely reduced in patients with rheumatoid arthritis treated with rituximab. *Arthritis Rheum*. 2010;62(1):75-81.
36. Confavreux C, Suissa S, Saddier P, Bourdès V, Vukusic S, Vaccines in Multiple Sclerosis Study Group. Vaccines in multiple sclerosis study group. Vaccinations and the risk of relapse in multiple sclerosis. *N Engl J Med*. 2001;344(5):319-326.
37. Michielsens B, Wilms G, Marchal G, Carton H. Serial magnetic resonance imaging studies with paramagnetic contrast medium: assessment of disease activity in patients with multiple sclerosis before and after influenza vaccination. *Eur Neurol*. 1990;30(5):258-259.
38. Seok HY, Shin HY, Kim JK, et al. The impacts of influenza infection and vaccination on exacerbation of myasthenia gravis. *J Clin Neurol*. 2017;13(4):325-330.
39. Zinman L, Thoma J, Kwong JC, Kopp A, Stukel TA, Juurlink DN. Safety of influenza vaccination in patients with myasthenia gravis: a population-based study. *Muscle Nerve*. 2009;40(6):947-951.
40. Dos Santos G, Tahrat H, Bekkat-Berkani R. Immunogenicity, safety, and effectiveness of seasonal influenza vaccination in patients with diabetes mellitus: a systematic review. *Hum Vaccine Immunother*. 2018;14(8):1853-1866.
41. Liberatore G, Manganelli F, Doneddu PE, et al. Chronic inflammatory demyelinating polyradiculoneuropathy: can a diagnosis be made in patients not fulfilling electrodiagnostic criteria? *Eur J Neurol*. 2021;28(2):620-629.
42. Svahn J, Petiot P, Antoine JC, et al. Anti-MAG antibodies in 202 patients: clinicopathological and therapeutic features. *J Neurol Neurosurg Psychiatry*. 2018;89(5):499-505.
43. Furer V, Rondaan C, Heijstek MW, et al. 2019 update of EULAR recommendations for vaccination in adult patients with autoimmune inflammatory rheumatic diseases. *Ann Rheum Dis*. 2020;79(1):39-52.
44. Fomin I, Caspi D, Levy V, et al. Vaccination against influenza in rheumatoid arthritis: the effect of disease modifying drugs, including TNF alpha blockers. *Ann Rheum Dis*. 2006;65(2):191-194.
45. Meroni PL, Zavaglia D, Girmenia C. Vaccinations in adults with rheumatoid arthritis in an era of new disease-modifying anti-rheumatic drugs. *Clin Exp Rheumatol*. 2018;36(2):317-328.
46. Agarwal N, Ollington K, Kaneshiro M, Frenck R, Melmed GY. Are immunosuppressive medications associated with decreased responses to routine immunizations? a systematic review. *Vaccine*. 2012;30(8):1413-1424.
47. Zbinden D, Manuel O. Influenza vaccination in immunocompromised patients: efficacy and safety. *Immunotherapy*. 2014;6(2):131-139.
48. Ciotti JR, Valtcheva MV, Cross AH. Effects of MS disease-modifying therapies on responses to vaccinations: a review. *Mult Scler Relat Disord*. 2020;45:102439.
49. Bingham CO, Looney RJ, Deodhar A, et al. Immunization responses in rheumatoid arthritis patients treated with rituximab: results from a controlled clinical trial. *Arthritis Rheum*. 2010;62(1):64-74.
50. Arvas A. Vaccination in patients with immunosuppression. *Turk Pediatr Ars*. 2014;49(3):181-185.
51. https://www.canada.ca/en/public-health/services/publications/healthy-living/canadian-immunization-guide-part-1-key-immunization-information/page-11-blood-products-human-immune-globulin-timing-immunization.html#shr-pg0
52. https://www.cdc.gov/vaccines/pubs/pinkbook/downloads/appendices/a/mmr_ig.pdf

53. https://wwwnc.cdc.gov/travel/yellowbook/2020/preparing-international-travelers/vaccination-and-immunoprophylaxis-general-recommendations
54. https://farmaci.agenziafarmaco.gov.it/aifa/servlet/PdfDownloadServlet?pdfFileName=footer_000802_041157_RCP.pdf&retry=0&sys=m0b1l3
55. https://farmaci.agenziafarmaco.gov.it/aifa/servlet/PdfDownloadServlet?pdfFileName=footer_003822_042804_RCP.pdf&retry=0&sys=m0b1l3
56. https://www.cdc.gov/vaccines/hcp/acip-recs/general-recs/immunocompetence.htm
57. Advisory Committee on Immunization Practices; Centers for Disease Control and Prevention (CDC). Immunization of health-care personnel: recommendations of the advisory committee on immunization practices (ACIP). *MMWR Recomm Rep*. 2011;60(RR-7):1-45.
58. Kumlien G, Ullström L, Losvall A, Persson LG, Tydén G. Clinical experience with a new apheresis filter that specifically depletes ABO blood group antibodies. *Transfusion*. 2006;46(9):1568-1575.
59. Valli PV, Puga Yung G, Fehr T, et al. Changes of circulating antibody levels induced by ABO antibody adsorption for ABO-incompatible kidney transplantation. *Am J Transplant*. 2009;9(5):1072-1080.
60. Schönermarck U, Kauke T, Jäger G, et al. Effect of apheresis for ABO and HLA desensitization on anti-measles antibody titers in renal transplantation. *J Transplant*. 2011;2011:869065.
61. Guptill JT, Juel VC, Massey JM, et al. Effect of therapeutic plasma exchange on immunoglobulins in myasthenia gravis. *Autoimmunity*. 2016;49(7):472-479.
62. https://www.who.int/publications/m/item/draft-landscape-of-covid-19-candidate-vaccines
63. Rawat K, Kumari P, Saha L. COVID-19 vaccine: a recent update in pipeline vaccines, their design and development strategies. *Eur J Pharmacol*. 2021;892:173751.
64. https://www.ema.europa.eu/en/human-regulatory/overview/public-health-threats/coronavirus-disease-covid-19/treatments-vaccines-covid-19.
65. Baden LR, El Sahly HM, Essink B, et al. Efficacy and safety of the mRNA-1273 SARS-CoV-2 vaccine. *N Engl J Med*. 2021;384(5):403-416.
66. https://www.gov.uk/government/news/oxford-universityastrazeneca-covid-19-vaccine-approved
67. https://www.ema.europa.eu/en/human-regulatory/overview/public-health-threats/coronavirus-disease-covid-19/treatments-vaccines/treatments-vaccines-covid-19-medicines-under-evaluation#covid-19-vaccines-section
68. Sadoff J, Le Gars M, Shukarev G, et al. Interim results of a phase 1–2a trial of Ad26.COV2.S Covid-19 vaccine. *N Engl J Med*. 2021; NEJMoa2034201. https://dx.doi.org/10.1056/NEJMoa2034201.
69. Kim D, Lee JY, Yang JS, Kim JW, Kim VN, Chang H. The architecture of SARS-CoV-2 transcriptome. *Cell*. 2020;181(4):914-921.e10.
70. Keech C, Albert G, Cho I, et al. Phase 1-2 trial of a SARS-CoV-2 recombinant spike protein nanoparticle vaccine. *N Engl J Med*. 2020; 383(24):2320-2332.
71. Logunov DY, Dolzhikova IV, Shcheblyakov DV, et al. Safety and efficacy of an rAd26 and rAd5 vector-based heterologous prime-boost COVID-19 vaccine: an interim analysis of a randomised controlled phase 3 trial in Russia. *Lancet*. 2021;S0140-6736(21):234-238.
72. Voysey M, Clemens SAC, Madhi SA, et al. Safety and efficacy of the ChAdOx1 nCoV-19 vaccine (AZD1222) against SARS-CoV-2: an interim analysis of four randomised controlled trials in Brazil, South Africa, and the UK. *Lancet*. 2021;397(10269):99-111.
73. Anderson EJ, Rouphael NG, Widge AT, et al. Safety and immunogenicity of SARS-CoV-2 mRNA-1273 vaccine in older adults. *N Engl J Med*. 2020;17(383(25)):2427-2438.
74. https://www.cdc.gov/coronavirus/2019-ncov/vaccines/recommendations/underlying-conditions.html
75. https://www.aifa.gov.it/domande-e-risposte-farmacovigilanza-vaccini-covid-19
76. https://www.worldometers.info/coronavirus/
77. https://coronavirus.jhu.edu/data/mortality
78. Immovilli P, Morelli N, Antonucci E, Radaelli G, Barbera M, Guidetti D. COVID-19 mortality and ICU admission: the Italian experience. *Crit Care*. 2020;24(1):228.
79. https://www.cdc.gov/coronavirus/2019-ncov/need-extra-precautions/people-with-medical-conditions.html

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