

CRA Recommendation on Three Doses of mRNA Vaccine for Preventing COVID-19

Version 1.0, November 23, 2021

The Canadian Rheumatology Association guideline panel suggests using a third dose of mRNA COVID-19 vaccination [BNT 162b2 (Pfizer-BioNTech) or mRNA-1273 (Moderna)] in persons aged 18 and older with autoimmune rheumatic disease.

(Conditional recommendation, very low certainty of the evidence about effects.)

Remarks:

- This recommendation is based on evidence for mRNA-1273 (Moderna).
- The recommendation needs to be viewed in the context of any guidance or restrictions for vaccine use set by national or provincial bodies, that may change over time. This includes guidance in people who have had a mixed initial vaccine series (2 different vaccines).

Primary justification:

- The panel judged that for the majority of patients the potential benefits outweigh the potential harms in people with autoimmune rheumatic diseases, although this may vary considerably by person, based on their medications, age, other comorbidities. The recommendation was graded as conditional because of very low certainty of the evidence about effects in the population of interest.

Primary implementation consideration for policy makers and providers:

- Persons with autoimmune rheumatic diseases should be able to access a third vaccine dose if desired, and not be required to take additional steps to obtain their vaccination.

[View the Evidence-to-Decision Framework \(EtD\)](#)

Justification

The CRA panel decided on a conditional recommendation for a third dose of mRNA COVID-19 vaccination in persons aged 18 and older with autoimmune rheumatic disease. The panel balanced the

very low certainty in the moderate benefits of a third dose (prevention of symptomatic infection) against the very low certainty of evidence for trivial harms. The panel discussed that the expected benefits are likely to vary considerably in individuals by current medications, age, and other comorbidities, but the expected harms are likely to be trivial. The decision to receive a third dose should be an individual discussion between a patient and their healthcare provider.

Subgroup considerations

The benefits of a third dose will likely vary considerably between individuals. Subgroups of patients in whom serological protection has been shown to be lower would be expected to have the greatest potential benefit from a third dose. Evidence is being accumulated on clinical outcomes and serological responses to COVID vaccination in patients with ARDs in a living systematic review (Whittle SL, Hazlewood GS et al. 2021), and will inform updates to this guideline.

As of October 2021, the evidence supports the following:

- People taking rituximab: Studies have consistently shown lower immunogenicity from the initial 2 doses of COVID-19 vaccination in people taking rituximab, which is consistent with other vaccines (Papp, Haraoui et al. 2019). Third doses should ideally be administered ≥ 4 -5 months after the last dose and at least 4 weeks prior to the subsequent dose of rituximab.
- People taking other DMARDs: There was a modest, but consistent reduction in serological response to COVID-19 vaccination in people with immune mediated inflammatory diseases across the six pooled case-control studies (see 'desirable effects' section of EtD). The evidence is less certain when analyzed by medication subgroups. In data from other (non-COVID) vaccines, methotrexate, mycophenolate mofetil, tofacitinib and prednisone (≥ 10 mg/day) have been shown to attenuate vaccine-induced responses (Papp, Haraoui et al. 2019). A single small study with abatacept and influenza vaccine also showed decreased immunogenicity (Ribeiro, Laurindo et al. 2013). It is likely that some medications (hydroxychloroquine, sulfasalazine) have little effect on serological response.

Implementation considerations

- As access to third doses is determined by provincial health authorities, it will be essential to ensure people with ARDs do not face unnecessary additional barriers. People with ARDs should not be required to obtain a physician letter as proof of an informed decision discussion.
- People with ARDs may have mobility limitations and appropriate access to vaccine clinics should be ensured.

Monitoring and evaluation

- Monitoring of vaccine uptake should occur in people with ARDs, including populations at risk of inequity. Low uptake may point to barriers to access or hesitancy.
- The frequency of serious adverse events, disease flares, and COVID-19 infection/serious outcomes should be followed in patients with ARDs who do and do not receive the vaccine.
- People with ARDs should be encouraged to track their immunization history using an online Canadian vaccination tracker, developed with funding support from the Public Health Agency of Canada (www.canimmunize.ca).

Research priorities

- Randomized controlled trial evidence for the effect of a third dose in ARDs as compared with placebo
- Observational evidence on the frequency of harms (in particular serious adverse events/serious disease flares) in people with ARD
- Evidence comparing the frequency of serious adverse events and autoimmune adverse events in people with ARDs to those without ARD
- Evidence on the benefits (both clinical outcomes and serological studies) in people with ARDs on different medications, including in pediatric populations
- Evidence on patient values and preferences for the benefits and harms across different patient populations
- Understanding vaccine hesitancy and barriers to vaccine access faced by persons with ARDs
- Understanding vaccine benefits and harms in populations at risk for inequities.

REFERENCES

1. ACR COVID-19 Vaccine Clinical Guidance Task Force. (2021). "COVID-19 Vaccine Clinical Guidance Summary for Patients with Rheumatic and Musculoskeletal Diseases." from <https://www.rheumatology.org/Portals/0/Files/COVID-19-Vaccine-Clinical-Guidance-Rheumatic-Diseases-Summary.pdf>.
2. Adamichou, C. and G. Bertsias (2017). "Flares in systemic lupus erythematosus: diagnosis, risk factors and preventive strategies." *Mediterr J Rheumatol* 28(1): 4-12.
3. Andersen, K. M., H. B. Mehta, N. Palamuttam, D. Ford, B. T. Garibaldi, P. G. Auwaerter, J. Segal and G. C. Alexander (2021). "Association Between Chronic Use of Immunosuppressive

- Drugs and Clinical Outcomes From Coronavirus Disease 2019 (COVID-19) Hospitalization: A Retrospective Cohort Study in a Large US Health System." *Clin Infect Dis*.
4. ANZMUSC. (2020 [version 0.3]). "An Australian Living Guideline for the Pharmacological Management of Inflammatory Arthritis." from <https://mskguidelines.org>.
 5. Arad, U., S. Tzadok, S. Amir, M. Mandelboim, E. Mendelson, I. Wigler, H. Sarbagil-Maman, D. Paran, D. Caspi and O. Elkayam (2011). "The cellular immune response to influenza vaccination is preserved in rheumatoid arthritis patients treated with rituximab." *Vaccine* 29(8): 1643-1648.
 6. Baden, L. R., H. M. El Sahly, B. Essink, K. Kotloff, S. Frey, R. Novak, D. Diemert, S. A. Spector, N. Rouphael, C. B. Creech, J. McGettigan, S. Kehtan, N. Segall, J. Solis, A. Brosz, C. Fierro, H. Schwartz, K. Neuzil, L. Corey, P. Gilbert, H. Janes, D. Follmann, M. Marovich, J. Mascola, L. Polakowski, J. Ledgerwood, B. S. Graham, H. Bennett, R. Pajon, C. Knightly, B. Leav, W. Deng, H. Zhou, S. Han, M. Ivarsson, J. Miller, T. Zaks and C. S. Group (2020). "Efficacy and Safety of the mRNA-1273 SARS-CoV-2 Vaccine." *N Engl J Med*.
 7. Boucher, V. G., S. Pelaez, C. Gemme, S. Labbe and K. L. Lavoie (2020). "Understanding factors associated with vaccine uptake and vaccine hesitancy in patients with rheumatoid arthritis: a scoping literature review." *Clin Rheumatol*.
 8. British Society for Rheumatology. (2020). "COVID-19 guidance." from <https://www.rheumatology.org.uk/practice-quality/covid-19-guidance>.
 9. Campochiaro, C., G. Trignani, A. Tomelleri, S. Cascinu, L. Dagna and C.-V. S. Group (2021). "Potential acceptance of COVID-19 vaccine in rheumatological patients: a monocentric comparative survey." *Ann Rheum Dis*.
 10. Canadian Rheumatology Association. (2020). "Canadian Rheumatology Association Position Statement on COVID-19 Vaccination." from https://mcusercontent.com/912adf891f7fdc4dfefb739ba/files/0df3fde1-a4a3-4f24-b6f5-eb4b3e053c11/CRA_Position_Statement_on_COVID_19_Vaccination_v2_FINAL.pdf.
 11. Chang, C. C., Y. S. Chang, W. S. Chen, Y. H. Chen and J. H. Chen (2016). "Effects of annual influenza vaccination on morbidity and mortality in patients with Systemic Lupus Erythematosus: A Nationwide Cohort Study." *Sci Rep* 6: 37817.
 12. Craven, J. (2021). "COVID-19 vaccine tracker." from <https://www.raps.org/news-and-articles/news-articles/2020/3/covid-19-vaccine-tracker>.
 13. Crenshaw, K. (1989). "Demarginalizing the Intersection of Race and Sex: A Black Feminist Critique of Antidiscrimination Doctrine, Feminist Theory and Antiracist Politics." *University of Chicago Legal Forum*: 139-168.
 14. Doran, M. F., C. S. Crowson, G. R. Pond, W. M. O'Fallon and S. E. Gabriel (2002). "Frequency of infection in patients with rheumatoid arthritis compared with controls: a population-based study." *Arthritis Rheum* 46(9): 2287-2293.
 15. Dougados, M., M. Soubrier, A. Antunez, P. Balint, A. Balsa, M. H. Buch, G. Casado, J. Detert, B. El-Zorkany, P. Emery, N. Hajjaj-Hassouni, M. Harigai, S. F. Luo, R. Kurucz, G. Maciel, E. M. Mola, C. M. Montecucco, I. McInnes, H. Radner, J. S. Smolen, Y. W. Song, H. E. Vonkeman, K. Winthrop and J. Kay (2014). "Prevalence of comorbidities in rheumatoid arthritis and evaluation

- of their monitoring: results of an international, cross-sectional study (COMORA)." *Ann Rheum Dis* 73(1): 62-68.
16. Durand, C., M. Eldoma, D. A. Marshall, N. Bansback and G. S. Hazlewood (2020). "Patient Preferences for Disease-modifying Antirheumatic Drug Treatment in Rheumatoid Arthritis: A Systematic Review." *J Rheumatol* 47(2): 176-187.
 17. Eisenberg, R. A., A. F. Jawad, J. Boyer, K. Maurer, K. McDonald, E. T. Prak and K. E. Sullivan (2013). "Rituximab-treated patients have a poor response to influenza vaccination." *J Clin Immunol* 33(2): 388-396.
 18. Favalli, E. G., F. Ingegnoli, R. Cimaz and R. Caporali (2021). "What is the true incidence of COVID-19 in patients with rheumatic diseases?" *Ann Rheum Dis* 80(2): e18.
 19. Fredi, M., I. Cavazzana, L. Moschetti, L. Andreoli, F. Franceschini and C.-S. G. Brescia Rheumatology (2020). "COVID-19 in patients with rheumatic diseases in northern Italy: a single-centre observational and case-control study." *Lancet Rheumatol* 2(9): e549-e556.
 20. Furer, V., C. Rondaan, M. W. Heijstek, N. Agmon-Levin, S. van Assen, M. Bijl, F. C. Breedveld, R. D'Amelio, M. Dougados, M. C. Kapetanovic, J. M. van Laar, A. de Thurah, R. B. Landewe, A. Molto, U. Muller-Ladner, K. Schreiber, L. Smolar, J. Walker, K. Warnatz, N. M. Wulffraat and O. Elkayam (2020). "2019 update of EULAR recommendations for vaccination in adult patients with autoimmune inflammatory rheumatic diseases." *Ann Rheum Dis* 79(1): 39-52.
 21. Gianfrancesco, M., K. L. Hyrich, S. Al-Adely, L. Carmona, M. I. Danila, L. Gossec, Z. Izadi, L. Jacobsohn, P. Katz, S. Lawson-Tovey, E. F. Mateus, S. Rush, G. Schmajuk, J. Simard, A. Strangfeld, L. Trupin, K. D. Wysham, S. Bhana, W. Costello, R. Grainger, J. S. Hausmann, J. W. Liew, E. Sirotych, P. Sufka, Z. S. Wallace, J. Yazdany, P. M. Machado, P. C. Robinson and C.-G. R. Alliance (2020). "Characteristics associated with hospitalisation for COVID-19 in people with rheumatic disease: data from the COVID-19 Global Rheumatology Alliance physician-reported registry." *Ann Rheum Dis* 79(7): 859-866.
 22. Goldblatt, F. and S. G. O'Neill (2013). "Clinical aspects of autoimmune rheumatic diseases." *Lancet* 382(9894): 797-808.
 23. Government of Canada. (2021). "Recommendations on the use of COVID-19 vaccines." Retrieved January 22, 2021, from <https://www.canada.ca/en/public-health/services/immunization/national-advisory-committee-on-immunization-naci/recommendations-use-covid-19-vaccines.html>.
 24. Guzman, J., K. Oen, A. M. Huber, K. Watanabe Duffy, G. Boire, N. Shiff, R. A. Berard, D. M. Levy, E. Stringer, R. Scuccimarri, K. Morishita, N. Johnson, D. A. Cabral, A. M. Rosenberg, M. Larche, P. Dancy, R. E. Petty, R. M. Laxer, E. Silverman, P. Miettunen, A. L. Chetaille, E. Haddad, K. Houghton, L. Spiegel, S. E. Turvey, H. Schmeling, B. Lang, J. Ellsworth, S. E. Ramsey, A. Bruns, J. Roth, S. Campillo, S. Benseler, G. Chedeville, R. Schneider, S. M. Tse, R. Bolaria, K. Gross, B. Feldman, D. Feldman, B. Cameron, R. Jurencak, J. Dorval, C. LeBlanc, C. St Cyr, M. Gibbon, R. S. Yeung, C. M. Duffy, L. B. Tucker and A.-O. i. Re (2016). "The risk and nature of flares in juvenile idiopathic arthritis: results from the ReACCh-Out cohort." *Ann Rheum Dis* 75(6): 1092-1098.
 25. Hazlewood, G. S., A. Loyola-Sanchez, V. Bykerk, P. M. Hull, D. Marshall, T. Pham, C. E. Barber, C. Barnabe, A. Sirois, J. Pope, O. Schier, D. Richards, L. Proulx and S. J. Bartlett

- (2021). "Patient and Rheumatologist Perspectives on Tapering DMARDs in Rheumatoid Arthritis: A Qualitative Study." *Rheumatology (Oxford)* [submitted].
26. Hazlewood, G. S., J. P. Pardo, C. Barnabe, O. Schieir, C. E. H. Barber, S. Bernatsky, I. Colmegna, C. Hitchon, M. Loeb, D. Mertz, L. Proulx, D. P. Richards, R. Scuccimarri, P. Tugwell, H. J. Schunemann, R. D. Mirza, A. L. Zhou, R. P. A. Nikolic, M. Thomas, H. Chase, M. Ejaredar and R. Nieuwlaat (2021). "Canadian Rheumatology Association Recommendation for the Use of COVID-19 Vaccination for Patients With Autoimmune Rheumatic Diseases." *J Rheumatol* 48(8): 1330-1339.
 27. Hitchon, C. A., G. Boire, B. Haraoui, E. Keystone, J. Pope, S. Jamal, D. Tin, C. Thorne, V. P. Bykerk and C. investigators (2016). "Self-reported comorbidity is common in early inflammatory arthritis and associated with poorer function and worse arthritis disease outcomes: results from the Canadian Early Arthritis Cohort." *Rheumatology (Oxford)* 55(10): 1751-1762.
 28. Hurd, K. and C. Barnabe (2017). "Systematic review of rheumatic disease phenotypes and outcomes in the Indigenous populations of Canada, the USA, Australia and New Zealand." *Rheumatol Int* 37(4): 503-521.
 29. Lazarus, J. V., S. C. Ratzan, A. Palayew, L. O. Gostin, H. J. Larson, K. Rabin, S. Kimball and A. El-Mohandes (2020). "A global survey of potential acceptance of a COVID-19 vaccine." *Nature Medicine*.
 30. Liu, M., Y. Gao, Y. Zhang, S. Shi, Y. Chen and J. Tian (2020). "The association between severe or dead COVID-19 and autoimmune diseases: A systematic review and meta-analysis." *J Infect* 81(3): e93-e95.
 31. Michelena, X., H. Borrell, M. Lopez-Corbeto, M. Lopez-Lasanta, E. Moreno, M. Pascual-Pastor, A. Erra, M. Serrat, E. Espartal, S. Anton, G. A. Anez, R. Caparros-Ruiz, A. Pluma, E. Trallero-Araguas, M. Barcelo-Bru, M. Almirall, J. J. De Agustin, J. Lladós, A. Julia and S. Marsal (2020). "Incidence of COVID-19 in a cohort of adult and paediatric patients with rheumatic diseases treated with targeted biologic and synthetic disease-modifying anti-rheumatic drugs." *Semin Arthritis Rheum* 50(4): 564-570.
 32. National Advisory Committee on Immunization (NACI). (December 23 2020). "Recommendations on the use of COVID-19 vaccines." from <https://www.canada.ca/en/public-health/services/immunization/national-advisory-committee-on-immunization-naci/recommendations-use-covid-19-vaccines.html>.
 33. Nixon, S. A. (2019). "The coin model of privilege and critical allyship: implications for health." *BMC Public Health* 19(1): 1637.
 34. O'Neill, J., H. Tabish, V. Welch, M. Petticrew, K. Pottie, M. Clarke, T. Evans, J. Pardo Pardo, E. Waters, H. White and P. Tugwell (2014). "Applying an equity lens to interventions: using PROGRESS ensures consideration of socially stratifying factors to illuminate inequities in health." *J Clin Epidemiol* 67(1): 56-64.
 35. Oren, S., M. Mandelboim, Y. Braun-Moscovici, D. Paran, J. Ablin, I. Litinsky, D. Comaneshter, D. Levartovsky, E. Mendelson, R. Azar, I. Wigler, A. Balbir-Gurman, D. Caspi and O. Elkayam (2008). "Vaccination against influenza in patients with rheumatoid arthritis: the effect of rituximab on the humoral response." *Ann Rheum Dis* 67(7): 937-941.

36. Papp, K. A., B. Haraoui, D. Kumar, J. K. Marshall, R. Bissonnette, A. Bitton, B. Bressler, M. Gooderham, V. Ho, S. Jamal, J. E. Pope, A. H. Steinhart, D. C. Vinh and J. Wade (2019). "Vaccination Guidelines for Patients With Immune-Mediated Disorders on Immunosuppressive Therapies." *J Cutan Med Surg* 23(1): 50-74.
37. Pianarosa, E., K. Chomistek, R. Hsiao, S. Anwar, V. Umaefulam, G. Hazlewood and C. Barnabe (2020). "Global Rural and Remote Patients with Rheumatoid Arthritis: A Systematic Review." *Arthritis Care Res (Hoboken)*.
38. Polack, F. P., S. J. Thomas, N. Kitchin, J. Absalon, A. Gurtman, S. Lockhart, J. L. Perez, G. Perez Marc, E. D. Moreira, C. Zerbini, R. Bailey, K. A. Swanson, S. Roychoudhury, K. Koury, P. Li, W. V. Kalina, D. Cooper, R. W. Frenck, Jr., L. L. Hammitt, O. Tureci, H. Nell, A. Schaefer, S. Unal, D. B. Tresnan, S. Mather, P. R. Dormitzer, U. Sahin, K. U. Jansen, W. C. Gruber and C. C. T. Group (2020). "Safety and Efficacy of the BNT162b2 mRNA Covid-19 Vaccine." *N Engl J Med* 383(27): 2603-2615.
39. Puges, M., P. Biscay, T. Barnetche, M. E. Truchetet, C. Richez, J. Seneschal, N. Gensous, E. Lazaro and P. Duffau (2016). "Immunogenicity and impact on disease activity of influenza and pneumococcal vaccines in systemic lupus erythematosus: a systematic literature review and meta-analysis." *Rheumatology (Oxford)* 55(9): 1664-1672.
40. Ribeiro, A. C., L. K. Guedes, J. C. Moraes, C. G. Saad, N. E. Aikawa, A. L. Calich, I. L. Franca, J. F. Carvalho, P. D. Sampaio-Barros, C. R. Goncalves, E. F. Borba, C. Timenetsky Mdo, A. R. Precioso, A. Duarte, E. Bonfa and I. M. Laurindo (2011). "Reduced seroprotection after pandemic H1N1 influenza adjuvant-free vaccination in patients with rheumatoid arthritis: implications for clinical practice." *Ann Rheum Dis* 70(12): 2144-2147.
41. Ribeiro, A. C., I. M. Laurindo, L. K. Guedes, C. G. Saad, J. C. Moraes, C. A. Silva and E. Bonfa (2013). "Abatacept and reduced immune response to pandemic 2009 influenza A/H1N1 vaccination in patients with rheumatoid arthritis." *Arthritis Care Res (Hoboken)* 65(3): 476-480.
42. Rothery, C., L. Bojke, G. Richardson, C. Bojke, A. Moverley, L. Coates, L. Thorp, R. Waxman and P. Helliwell (2016). "A discrete choice experiment to explore patients' willingness to risk disease relapse from treatment withdrawal in psoriatic arthritis." *Clin Rheumatol* 35(12): 2967-2974.
43. Sadoff, J., G. Gray, A. Vandebosch, V. Cardenas, G. Shukarev, B. Grinsztejn, P. A. Goepfert, C. Truyers, H. Fennema, B. Spiessens, K. Offergeld, G. Scheper, K. L. Taylor, M. L. Robb, J. Treanor, D. H. Barouch, J. Stoddard, M. F. Ryser, M. A. Marovich, K. M. Neuzil, L. Corey, N. Cauwenberghs, T. Tanner, K. Hardt, J. Ruiz-Guinazu, M. Le Gars, H. Schuitemaker, J. Van Hoof, F. Struyf, M. Douguih and E. S. Group (2021). "Safety and Efficacy of Single-Dose Ad26.COV2.S Vaccine against Covid-19." *N Engl J Med*.
44. Safiri, S., A. A. Kolahi, D. Hoy, E. Smith, D. Bettampadi, M. A. Mansournia, A. Almasi-Hashiani, A. Ashrafi-Asgarabad, M. Moradi-Lakeh, M. Qorbani, G. Collins, A. D. Woolf, L. March and M. Cross (2019). "Global, regional and national burden of rheumatoid arthritis 1990-2017: a systematic analysis of the Global Burden of Disease study 2017." *Ann Rheum Dis* 78(11): 1463-1471.
45. Sallam, M. (2021). "COVID-19 vaccine hesitancy worldwide: a systematic review of vaccine acceptance rates." *medRxiv: 2020.2012.2028.20248950*.

46. Sandmann, F., N. Davies, A. Vassall, W. J. Edmunds and M. Jit (2020). "The potential health and economic value of SARS-CoV-2 vaccination alongside physical distancing in the UK: transmission model-based future scenario analysis and economic evaluation." medRxiv: 2020.2009.2024.20200857.
47. Shigayeva, A., W. Rudnick, K. Green, D. K. Chen, W. Demczuk, W. L. Gold, J. Johnstone, I. Kitai, S. Kraiden, R. Lovinsky, M. Muller, J. Powis, N. Rau, S. Walmsley, G. Tyrrell, A. Bitnun, A. McGeer and N. Toronto Invasive Bacterial Diseases (2016). "Invasive Pneumococcal Disease Among Immunocompromised Persons: Implications for Vaccination Programs." Clin Infect Dis 62(2): 139-147.
48. Stamp, L. K., S. J. Chan, C. Marra, C. Helme and G. J. Treharne (2019). "Tapering biologic therapy for people with rheumatoid arthritis in remission: A review of patient perspectives and associated clinical evidence." Musculoskeletal Care 17(3): 161-169.
49. Strangfeld, A., M. Schafer, M. A. Gianfrancesco, S. Lawson-Tovey, J. W. Liew, L. Ljung, E. F. Mateus, C. Richez, M. J. Santos, G. Schmajuk, C. A. Scire, E. Sirocich, J. A. Sparks, P. Sufka, T. Thomas, L. Trupin, Z. S. Wallace, S. Al-Adely, J. Bachiller-Corral, S. Bhana, P. Cacoub, L. Carmona, R. Costello, W. Costello, L. Gossec, R. Grainger, E. Hachulla, R. Hasseli, J. S. Hausmann, K. L. Hyrich, Z. Izadi, L. Jacobsohn, P. Katz, L. Kearsley-Fleet, P. C. Robinson, J. Yazdany, P. M. Machado, C.-G. R. Alliance and C.-G. R. A. Consortium (2021). "Factors associated with COVID-19-related death in people with rheumatic diseases: results from the COVID-19 Global Rheumatology Alliance physician-reported registry." Ann Rheum Dis.
50. Urowitz, M. B., D. D. Gladman, V. Farewell, J. Su, J. Romero-Diaz, S. C. Bae, P. R. Fortin, J. Sanchez-Guerrero, A. E. Clarke, S. Bernatsky, C. Gordon, J. G. Hanly, D. J. Wallace, D. A. Isenberg, A. Rahman, J. T. Merrill, E. Ginzler, G. S. Alarcon, W. W. Chatham, M. A. Petri, I. N. Bruce, M. A. Khamashta, C. Aranow, M. A. Dooley, S. Manzi, R. Ramsey-Goldman, O. Nived, A. Jonsen, K. Steinsson, A. A. Zoma, G. Ruiz-Irastorza, S. S. Lim, K. C. Kalunian, M. Inanc, R. van Vollenhoven, M. Ramos-Casals, D. L. Kamen, S. Jacobsen, C. A. Peschken, A. Askanase and T. Stoll (2020). "Accrual of Atherosclerotic Vascular Events in a Multicenter Inception Systemic Lupus Erythematosus Cohort." Arthritis Rheumatol 72(10): 1734-1740.
51. Valeria Valerio, H. C. S., Emily G McDonald, Alyson Turner, Charles Frenette, Marie Hudson, Brian J Ward, Ines Colmegna "High Frequency of COVID Vaccine Hesitancy Among People Immunized for Influenza." [unpublished].
52. van Herwaarden, N., A. van der Maas, M. J. Minten, F. H. van den Hoogen, W. Kievit, R. F. van Vollenhoven, J. W. Bijlsma, B. J. van den Bemt and A. A. den Broeder (2015). "Disease activity guided dose reduction and withdrawal of adalimumab or etanercept compared with usual care in rheumatoid arthritis: open label, randomised controlled, non-inferiority trial." BMJ 350: h1389.
53. Voysey, M., S. A. C. Clemens, S. A. Madhi, L. Y. Weckx, P. M. Folegatti, P. K. Aley, B. Angus, V. L. Baillie, S. L. Barnabas, Q. E. Bhorat, S. Bibi, C. Briner, P. Cicconi, A. M. Collins, R. Colin-Jones, C. L. Cutland, T. C. Darton, K. Dheda, C. J. A. Duncan, K. R. W. Emary, K. J. Ewer, L. Fairlie, S. N. Faust, S. Feng, D. M. Ferreira, A. Finn, A. L. Goodman, C. M. Green, C. A. Green, P. T. Heath, C. Hill, H. Hill, I. Hirsch, S. H. C. Hodgson, A. Izu, S. Jackson, D. Jenkin, C. C. D. Joe, S. Kerridge, A. Koen, G. Kwatra, R. Lazarus, A. M. Lawrie, A. Lelliott, V. Libri, P. J. Lillie, R. Mallory, A. V. A. Mendes, E. P. Milan, A. M. Minassian, A. McGregor, H. Morrison, Y. F.

- Mujadidi, A. Nana, P. J. O'Reilly, S. D. Padayachee, A. Pittella, E. Plested, K. M. Pollock, M. N. Ramasamy, S. Rhead, A. V. Schwarzbald, N. Singh, A. Smith, R. Song, M. D. Snape, E. Sprinz, R. K. Sutherland, R. Tarrant, E. C. Thomson, M. E. Torok, M. Toshner, D. P. J. Turner, J. Vekemans, T. L. Villafana, M. E. E. Watson, C. J. Williams, A. D. Douglas, A. V. S. Hill, T. Lambe, S. C. Gilbert, A. J. Pollard and C. V. T. G. Oxford (2021). "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* 397(10269): 99-111.
54. Yun, H., S. Yang, L. Chen, F. Xie, K. Winthrop, J. W. Baddley, K. G. Saag, J. Singh and J. R. Curtis (2016). "Risk of Herpes Zoster in Autoimmune and Inflammatory Diseases: Implications for Vaccination." *Arthritis Rheumatol* 68(9): 2328-2337.