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2.7.5.1 LITERATURE REFERENCES

Agrawal AS, Tao X, Algaissi A, Garron T, Narayanan K, Peng BH, et al. Immunization with inactivated Middle East respiratory syndrome coronavirus vaccine leads to lung immunopathology on challenge with live virus. *Hum Vaccin Immunother.* 2016;12(9):2351-56.

Anderson EJ, Rouphael NG, Widge AT, Jackson LA, Roberts PC, Makhene M, et al; mRNA-1273 Study Group. Safety and immunogenicity of SARS-CoV-2 mRNA-1273 vaccine in older adults. *N Engl J Med.* 2020;383(25):2427-38.

Baden LR, El Sahly HM, Essink B, Kotloff K, Frey S, Novak R, et al; COVE Study Group. Efficacy and safety of the mRNA-1273 SARS-CoV-2 vaccine. *N Engl J Med.* 2021;384(5):403-16.

Biologics Effectiveness and Safety (BEST) Initiative. Background Rates of Adverse Events of Special Interest for COVID-19 Vaccine Safety Monitoring – Draft Protocol. Dec 2020. [cited 2021 Jun 10] Available from: BEST Initiative <https://www.bestinitiative.org/wp-content/uploads/2021/01/C19-Vaccine-Safety-AESI-Background-Rate-Protocol-2020.pdf>

Bolles M, Deming D, Long K, Agnihothram S, Whitmore A, Ferris M et al. A double-inactivated severe acute respiratory syndrome coronavirus vaccine provides incomplete protection in mice and induces increased eosinophilic proinflammatory pulmonary response upon challenge. *J Virol.* 2011;85(23):12201-15.

Carfi A, Bernabei R, Landi F; Gemelli Against COVID-19 Post-Acute Care Study Group. Persistent symptoms in patients after acute COVID-19. *JAMA.* 2020;324(6):603-5.

Centers for Disease Control and Prevention (CDC) [homepage on the Internet]. Washington, D.C.: U.S. Department of Health & Human Services. 2021a [cited 2021 Jun 10]. Available from: <https://covid.cdc.gov/covid-data-tracker/#vaccinations>

Centers for Disease Control and Prevention (CDC). Science Brief: SARS-CoV-2 Transmission. May 2021a. [cited 2021 Jun 11]. Available from: <https://www.cdc.gov/coronavirus/2019-ncov/science/science-briefs/sars-cov-2-transmission.html>.

Centers for Disease Control and Prevention (CDC) [homepage on the Internet]. Washington, D.C.: U.S. Department of Health & Human Services. 2021b [updated 2021 Mar 01; cited 2021 Jun 10]. Available from: <https://www.cdc.gov/nchs/fastats/leading-causes-of-death.htm>

Centers for Disease Control and Prevention (CDC). People with Certain Medical Conditions. May 2021b. [cited 2021 Jun 11]. Available from: <https://www.cdc.gov/coronavirus/2019-ncov/need-extra-precautions/people-with-medical-conditions.html>.

Centers for Disease Control and Prevention (CDC) [homepage on the Internet]. Washington, D.C.: U.S. Department of Health & Human Services. 2021c [data retrieved on 2021 Jul 01]. Available from: <http://wonder.cdc.gov>.

Chen Y, Lu S, Jia H, Deng Y, Zhou J, Huang B, et al. A novel neutralizing monoclonal antibody targeting the N-terminal domain of the MERS-CoV spike protein. *Emerg Microbes Infect.* 2017;6(5):e37.

Chin J, Magoffin RL, Shearer LA, Schieble JH, Lennette EH. Field evaluation of a respiratory syncytial virus vaccine and a trivalent parainfluenza virus vaccine in a pediatric population. *Am J Epidemiol.* 1969;89(4):449–63.

Chu L, McPhee R, Huang W, Bennett H, Pajon R, Nestorova B, et al; mRNA-1273 Study Group. A preliminary report of a randomized controlled phase 2 trial of the safety and immunogenicity of mRNA-1273 SARS-CoV-2 vaccine. *Vaccine.* 2021;39(20):2791-9.

Corbett KS, Edwards DK, Leist SR, Abiona OM, Boyoglu-Barnum S, Gillespie RA, et al. SARS-CoV-2 mRNA vaccine development enabled by prototype pathogen preparedness. *Nature.* 2020a; 586(7830):567-71. doi:10.1038/s41586-020-2622-0.

Corbett KS, Flynn B, Foulds KE, Francica JR, Boyoglu-Barnum S, Werner AP, et al. Evaluation of the mRNA-1273 vaccine against SARS-CoV-2 in nonhuman primates. *N Engl J Med.* 2020b;383(16):1544-55. doi: 10.1056/NEJMoa2024671.

Corti D, Zhao J, Pedotti M, Simonelli L, Agnihothram S, Fett C, et al. Prophylactic and postexposure efficacy of a potent human monoclonal antibody against MERS coronavirus. *Proc Natl Acad Sci U S A.* 2015;112(33):10473-8.

Department of Health and Human Services (DHHS), Food and Drug Administration, Center for Biologics and Evaluation Research, Center for Drug Evaluation and Research (US). Enhancing the Diversity of Clinical Trial Populations - Eligibility Criteria, Enrollment Practices, and Trial Designs Draft Guidance for Industry. Jun 2019. [cited 2021 Jun 10]. Available from: <https://fda.report/media/127739/21604886dft.pdf>

Department of Health and Human Services (DHHS), Food and Drug Administration, Center for Biologics and Evaluation Research (US). Guidance for industry: Development and Licensure of Vaccines to Prevent COVID-19. June 2020. [cited 2021 Jun 11]. Available from: <https://www.fda.gov/regulatory-information/search-fda-guidance-documents/development-and-licensure-vaccines-prevent-covid-19>.

Department of Health and Human Services (DHHS), Food and Drug Administration, Center for Biologics Evaluation and Research. Guidance for industry: Emergency Use Authorization for Vaccines to Prevent COVID-19. May 2021. [cited 2021 Jul 14]. Available from: <https://www.fda.gov/regulatory-information/search-fda-guidance-documents/emergency-use-authorization-vaccines-prevent-covid-19>.

Desmet CJ, Ishii KJ. Nucleic acid sensing at the interface between innate and adaptive immunity in vaccination. *Nat Rev Immunol*. 2012;12(7):479-91.

Dodd C, Willame C. Rapid safety assessment of COVID-19 vaccines in electronic healthcare databases: a protocol template from the ACCESS project. 2020 [cited 2021 Jun 10]. Available from: <https://vac4eu.org/wp-content/uploads/2021/02/3b.Rapid-assessment-of-COVID-19-vaccines-safety-concerns-through-electronic-health-records-a-protocol-template-from-the-ACCESS-project-.pdf>

Dong E, Du H, Gardner L. An interactive web-based dashboard to track COVID-19 in real time. *Lancet Infect Dis*. 2020;20(5):533-534. doi: 10.1016/S1473-3099(20)30120-1.

Doria-Rose N, Suthar MS, Makowski M, O'Connell S, McDermott AB, Flach B, et al; mRNA-1273 Study Group. Antibody persistence through 6 months after the second dose of mRNA-1273 vaccine for COVID-19. *N Engl J Med*. 2021;384(23):2259-61.

Escalante E, Golden RL, Mason DJ. Social isolation and loneliness: Imperatives for health care in a post-COVID world. *JAMA*. 2021;325(6):520–1. doi:10.1001/jama.2021.0100.

European Centres for Disease Prevention and Control (ECDC) [homepage on the Internet]. Solna, Sweden: European Union. 2021 [data retrieved on 2021 Jul 01]. Available from: <https://qap.ecdc.europa.eu/public/extensions/COVID-19/vaccine-tracker.html#distribution-tab>

European Medicines Agency (EMA), Heads of Medicines Agencies. Guideline on good pharmacovigilance practices (GVP) Module IX – Signal management (Rev 1). Oct 2017. [cited 2021 Jun]. Available from: https://www.ema.europa.eu/en/documents/scientific-guideline/guideline-good-pharmacovigilance-practices-gvp-module-ix-signal-management-rev-1_en.pdf

Fechter P, Brownlee GG. Recognition of mRNA cap structures by viral and cellular proteins. *J Gen Virol.* 2005;86(Pt 5):1239-49.

Federal Office of Public Health [homepage on the Internet]. Liebefeld, Switzerland. 2021 [data retrieved on 2021 Jul 01]. Available from: <https://www.covid19.admin.ch/en/epidemiologic/vacc-doses>

Gargano JW, Wallace M, Hadler SC, Langley G, Su JR, Oster ME, et al. Use of mRNA COVID-19 vaccine after reports of myocarditis among vaccine recipients: update from the Advisory Committee on Immunization Practices – United States, June 2021. *MMWR US Department of Health and Human Services Centers for Disease Control and Prevention.* July 9, 2021; 70(27):977-982.

Grifoni A, Weiskopf D, Ramirez SI, Mateus J, Dan JM, Moderbacher CR, et al. Targets of T cell responses to SARS-CoV-2 coronavirus in humans with COVID-19 disease and unexposed individuals. *Cell.* 2020 Jun 25;181(7):1489-501.

Gubernot D, Jazwa A, Niu M, Baumblatt J, Gee J, Moro P, et al. U.S. population-based background incidence rates of medical conditions for use in safety assessment of COVID-19 vaccines. *Vaccine.* 2021;39(28):3666-3677. doi: 10.1016/j.vaccine.2021.05.016.

Halpin, SJ, McIvor, C, Whyatt, G, Adams A, Harvey O, McLean L, et al. Postdischarge symptoms and rehabilitation needs in survivors of COVID-19 infection: A cross-sectional evaluation. *J Med Virol.* 2021;93(2):1013-22.

Harvey, W.T., Carabelli, A.M., Jackson, B. et al. SARS-CoV-2 variants, spike mutations and immune escape. *Nat Rev Microbiol* 19, 409–424 (2021).

Havervall S, Rosell A, Phillipson M, Mangsbo SM, Nilsson P, Hober S, et al. Symptoms and functional impairment assessed 8 months after mild COVID-19 among health care workers. *JAMA.* 2021;325(19):2015-16.

Haynes B, Corey L, Fernandes P, et al. Prospects for a safe COVID-19 vaccine. *Sci Transl Med.* 2020 Nov 4;12(568):eabe0948.

Health Canada [homepage on the Internet]. Ottawa, Ontario. Minister of Health, Health Portfolio. 2021 [data retrieved on 2021 Jul 01]. Available from: <https://health-infobase.canada.ca/covid-19/vaccination-coverage/>

Huang Y, Tan C, Wu J, Chen M, Wang Z, Luo L, et al. Impact of coronavirus disease 2019 on pulmonary function in early convalescence phase. *Respir Res.* 2020;21(1):163.

doi:10.1186/s12931-020-01429-6.

Jackson LA, Anderson EJ, Rouphael NG, Roberts PC, Makhene M, Coler RN, et al. An mRNA vaccine against SARS-CoV-2 - preliminary report. *N Engl J Med.* 2020;383(20):1920-31.

Johansson MA, Quandelacy TM, Kada S, Prasad PV, Steele M, et al. SARS-CoV-2 transmission from people without COVID-19 symptoms. *JAMA Netw Open.* 2021;4(1):e2035057.

doi:10.1001/jamanetworkopen.2020.35057.

Johnson BH, Palmer L, Gatwood J, Lenhart G, Kawai K, Acosta CJ. Annual incidence rates of herpes zoster among an immunocompetent population in the United States. *BMC Infect Dis.* 2015;15:502. doi: 10.1186/s12879-015-1262-8.

Johnson RF, Bagci U, Keith L, Tang X, Mollura DJ, Zeitlin L, et al. 3B11-N, a monoclonal antibody against MERS-CoV, reduces lung pathology in rhesus monkeys following intratracheal inoculation of MERS-CoV Jordan-n3/2012. *Virology.* 2016;490:49-58.

Kang M, An J. Viral Myocarditis. 2021 May 10. In: StatPearls [Internet]. Treasure Island (FL): StatPearls Publishing; 2021 Jan. PMID: 29083732. Available from:

<https://www.ncbi.nlm.nih.gov/books/NBK459259/>

Karikó K, Buckstein M, Ni H, Weissman D. Suppression of RNA recognition by Toll-like receptors: the impact of nucleoside modification and the evolutionary origin of RNA. *Immunity.* 2005;23(2):165-75.

Kim HW, Canchola JG, Brandt CD, Pyles G, Chanock RM, Jensen K, et al. Respiratory syncytial virus disease in infants despite prior administration of antigenic inactivated vaccine. *Am J Epidemiol.* 1969 Apr;89(4):422-34.

Kim Y, Lee H, Park K, Park S, Lim JH, So MK, et al. Selection and characterization of monoclonal antibodies targeting Middle East respiratory syndrome coronavirus through a human synthetic fab phage display library panning. *Antibodies (Basel).* 2019;8(3):42.

Kozak M. An analysis of vertebrate mRNA sequences: intimations of translational control. *J Cell Biol.* 1991;115(4):887-903.

Law B, Sturkenboom M. Safety Platform for Emergency vACcines -D2.3 Priority List of Adverse Events of Special Interest: COVID-19. 2020. [cited 2021 Jun 10]. Available from:

https://brightoncollaboration.us/wp-content/uploads/2020/06/SPEAC_D2.3_V2.0_COVID-19_20200525_public.pdf

Li X, Ostropolets A, Makadia R, Shaoibi A, Rao G, Sena AG, et al. Characterizing the incidence of adverse events of special interest for COVID-19 vaccines across eight countries: a multinational network cohort study. medRxiv. 2021:2021.03.25.21254315. doi: 10.1101/2021.03.25.21254315.

Logue, JK, Franko NM, McCulloch DJ, McDonald D, Magedson A, Wolf CR, et al. Sequelae in adults at 6 months after COVID-19 infection. JAMA Netw Open. 2021;4(2): e210830.

Mansfield KE, Mathur R, Tazare J, Henderson AD, Mulick AR, Carreira H, et al. Indirect acute effects of the COVID-19 pandemic on physical and mental health in the UK: a population-based study. Lancet Digit Health. 2021;3(4):e217-e230. [https://doi.org/10.1016/S2589-7500\(21\)00017-0](https://doi.org/10.1016/S2589-7500(21)00017-0).

Moderna TX, Inc. mRNA-1273. Investigator's brochure, 6th ed. Cambridge (MA); 2021a. 66p.

Moderna TX, Inc. (Cambridge; MA). mRNA-1273. Moderna mRNA-1273 biomarker concordance analysis report for protocol mRNA-1273-P301.; 2021b Apr 29. Protocol No.: mRNA-1273-P301. 25p.

Munoz FM, Cramer JP, Dekker CL, Dudley MZ, Graham BS, Gurwith M, et al. Vaccine-associated enhanced disease: Case definition and guidelines for data collection, analysis, and presentation of immunisation safety data. Vaccine. 2021 May 21;39(22):3053-3066. doi: 10.1016/j.vaccine.2021.01.055.

Our World in Data [homepage on the Internet]. University of Oxford. 2021 [data retrieved on 2021 Jul 01]. Available from: <https://ourworldindata.org/covid-vaccinations>

Peleg Y, Kudose S, D'Agati V, Siddall E, Ahmad S, Nickolas T, et al. Acute kidney injury due to collapsing glomerulopathy following COVID-19 infection. Kidney Int Rep. 2020;5(6):940–45.

Peng Y, Mentzer AJ, Liu G, Yao X, Yin Z, Dong D, et al. Broad and strong memory CD4+ and CD8+ T-cells induced by SARS-CoV-2 in UK convalescent COVID-19 patients. Nat Immunol. 2020 Nov;21(11):1336-45. doi: 10.1038/s41590-020-0782-6. [Online ahead of print].

Puntmann VO, Carerj ML, Wieters I, Fahim M, Arendt C, Hoffman J, et al. Outcomes of cardiovascular magnetic resonance imaging in patients recently recovered from coronavirus disease 2019 (COVID-19). JAMA Cardiol. 2020; 5(11):1265-73.

Rajpal S, Tong MS, Borchers J, Zareba KM, Obarski TP, Simonetti OP, et al. Cardiovascular magnetic resonance findings in competitive athletes recovering from COVID-19 infection. JAMA Cardiol. 2021;6(1):116-18. doi:10.1001/jamacardio.2020.4916.

Ritchie H, Ortiz-Ospina E, Beltekian D, Mathieu E, Hassell J, Macdonald B, et al. (2021) - "Coronavirus Pandemic (COVID-19)". [Online Resource] Published online at OurWorldInData.org. Available from: <https://ourworldindata.org/coronavirus>.

Rozenski J, Crain PF, McCloskey JA. The RNA Modification Database: 1999 update. *Nucleic Acids Res.* 1999;27(1):196-7.

Rüggeberg JU, Gold MS, Bayas J-M, Blum MD, Bonhoeffer J, Friedlander S, et al. Anaphylaxis: case definition and guidelines or data collection, analysis, and presentation of immunization safety data. *Vaccine.* 2007;25 (31):5675-5684. doi: 10.1016/j.vaccine.2007.02.064.

Sardari A, Tabarsi P, Borhany H, Mohiaddin R, Houshmand G. Myocarditis detected after COVID-19 recovery. *Eur Heart J Cardiovasc Imaging.* 2021; 22(1):131-32. doi: 10.1093/ehjci/jeaa166.

Sekine T, Perez-Potti A, Rivera-Ballesteros O, Stralin K, Gorin JB, Olsson A, et al. Robust T cell immunity in convalescent individuals with asymptomatic or mild COVID-19. *Cell.* 2020 Oct 1:183(1):158-68.

Shimabukuro T. Enhanced safety monitoring for COVID-19 vaccines in early phase vaccination. Advisory Committee on Immunization Practices (ACIP); 2020 Sep 22; Atlanta, GA: Department of Health and Human Services, Centers For Disease Control And Prevention. 2020.

Spencer AJ, McKay PF, Belij-Rammerstorfer S, Ulaszewska M, Bissett CD, Hu K, et al. Heterologous vaccination regimens with self-amplifying RNA and adenoviral COVID vaccines induce robust immune responses in mice. *Nat Commun.* 2021;12(1):2893. doi:10.1038/s41467-021-23173-1.

Thomas SJ and Yoon IK. A review of Dengvaxia[®]: development to deployment. *Hum Vaccin Immunother.* 2019;15(10), 2295-314.

Tseng C-T, Sbrana E, Iwata-Yoskikawa N, Newman PC, Garron T, Atmar RL, et al. Immunization with SARS coronavirus vaccines leads to pulmonary immunopathology on challenge with the SARS virus. *PloS One.* 2012;7(4):e35421.

United States Census Bureau. National Population by Characteristics:2010-2019. Annual estimates of the resident population by Sex, Race, and Hispanic origin: April 1, 2010 to July 1, 2019 [Internet]. Washington (DC). [revised 2021 Apr 20; accessed 2021 Jun 23]. Available from: <https://www.census.gov/data/tables/time-series/demo/popest/2010s-national-detail.html>.

Wang L, Shi W, Chappell JD, Joyce MG, Zhang Y, Kanekiyo M, et al. Importance of neutralizing monoclonal antibodies targeting multiple antigenic sites on the Middle East respiratory syndrome coronavirus spike glycoprotein to avoid neutralization escape. *J Virol*. 2018;92(10):e02002-17.

Wang L, Shi W, Joyce MG, Modjarrad K, Zhang Y, Leung K, et al. Evaluation of candidate vaccine approaches for MERS-CoV. *Nat Commun*. 2015;6:7712.

Weiskopf D, Schmitz KS, Raadsen MP, Grifoni A, Okba N, Endeman H, et al. Phenotype and kinetics of SARS-CoV-2-specific T cells in COVID-19 patients with acute respiratory distress syndrome. *Sci Immunol*. 2020 Jun 26;5(48):eabd2071.

Widge AT, Roupael NG, Jackson LA, Anderson EJ, Roberts PC, Makhene M, et al; mRNA-1273 Study Group. Durability of responses after SARS-CoV-2 mRNA-1273 vaccination. *N Engl J Med*. 2021;384(1):80-2.

Widjaja I, Wang C, van Haperen R, Gutiérrez-Álvarez J, van Dieren B, Okba NMA, et al. Towards a solution to MERS: protective human monoclonal antibodies targeting different domains and functions of the MERS-coronavirus spike glycoprotein. *Emerg Microbes Infect*. 2019;8(1):516-30.

World Health Organization. Dengue vaccine: WHO position paper, September 2018 – recommendations. *Vaccine*. 2019;37(35):4848-49.

World Health Organization (WHO). Update 5 – general information on the virus and the outbreak. Feb 2020a. [cited 2021 Jun 11]. Available from: <https://www.who.int/publications/m/item/update-5---general-information-on-the-virus-and-the-outbreak>.

World Health Organization (WHO). WHO Director-General’s opening remarks at the media briefing on COVID-19 – 11 Mar 2020. Mar 2020b. [cited 2021 Jun 11]. Available from: <https://www.who.int/director-general/speeches/detail/who-director-general-s-opening-remarks-at-the-media-briefing-on-covid-19---11-march-2020>.

World Health Organization (WHO). WHO coronavirus disease (COVID-19) dashboard. 2021a. [cited 2021 Jul 27]. Available from: <https://covid19.who.int/>.

World Health Organization (WHO). Update 54 – Clinical long-term effects of COVID-19. Mar 2021b. [cited 2021 Jun 11]. Available from: <https://www.who.int/publications/m/item/update-54-clinical-long-term-effects-of-covid-19>.

Yasui F, Kai C, Kitabatake M, Inoue S, Yoneda M, Yokochi S, et al. Prior Immunization with severe acute respiratory syndrome (SARS) – associated coronavirus (SARS-CoV) nucleocapsid protein causes severe pneumonia in mice infected with SARS-CoV. *J Immunol.* 2008;181(9):6337-48.

Yu X, Zhang S, Jiang L, Cui Y, Li D, Wang D, et al. Structural basis for the neutralization of MERS-CoV by a human monoclonal antibody MERS-27. *Sci Rep.* 2015;5:13133.

Zhao YM, Shang YM, Song WB, Li QQ, Xie H, Xu QF, et al. Follow-up study of the pulmonary function and related physiological characteristics of COVID-19 survivors three months after recovery. *EClinicalMedicine.* 2020;25:100463. doi:10.1016/j.eclinm.2020.100463.