Keeping Abreast of the Development of Vaccines to Prevent COVID-19: What Clinicians Need to Know Tweetorial #3 References

Tweet Three

Abdool Karim SS, de Oliveira T. N Engl J Med. 2021;384(19):1866-1868.

Advisory Committee on Immunization Practices. ACIP evidence to recommendations for use of Pfizer-BioNTech COVID-19 vaccine under an emergency use authorization. CDC website. Reviewed December 17, 2020. Accessed April 14, 2021. https://www.cdc.gov/vaccines/acip/recs/grade/covid-19-pfizer-biontechetr.html

Centers for Disease Control and Prevention. Science brief: emerging SARS-CoV-2 variants. CDC website. Updated January 28, 2021. Accessed April 14, 2021. https://www.cdc.gov/coronavirus/2019-ncov/science/science-briefs/scientific-brief-emerging-variants.html

Liu Y, Liu J, Xia H, et al. Neutralizing activity of BNT162b2-elicited serum. *N Engl J Med.* 2021;384(15):1466-1468. doi:10.1056/NEJMc2102017

Mahase E. COVID-19: where are we on vaccines and variants? BMJ. 2021;372:n597. doi:10.1136/bmj.n597

Moderna Inc. Moderna COVID-19 vaccine retains neutralizing activity against emerging variants first identified in the UK and the Republic of South Africa. Moderna website. January 25, 2021. Accessed April 14, 2021. https://investors.modernatx.com/news-releases/news-release-details/moderna-covid-19-vaccine-retains-neutralizing-activity-against

Oliver SE, Gargano JW, Marin M, et al. The Advisory Committee on Immunization Practices' interim recommendation for use of Pfizer-BioNTech COVID-19 Vaccine — United States, December 2020. *MMWR Morb Mortal Wkly Rep.* 2020;69(50):1922-1924. doi:10.15585/mmwr.mm6950e2

Oliver SE, Gargano JW, Marin M, et al. The Advisory Committee on Immunization Practices' interim recommendation for use of Moderna COVID-19 Vaccine — United States, December 2020. *MMWR Morb Mortal Wkly Rep.* 2021;69(5152):1653-1656. doi:10.15585/mmwr.mm695152e1

Pfizer Inc. Pfizer and Biontech confirm high efficacy and no serious safety concerns through up to six months following second dose in updated topline analysis of landmark COVID-19 vaccine study. Pfizer website. April 1, 2021. Accessed April 14, 2021. https://www.pfizer.com/news/press-release/press-release-detail/pfizer-and-biontech-confirm-high-efficacy-and-no-serious

Planas D, Bruel T, Grzelak L, et al. Sensitivity of infectious SARS-CoV-2 B.1.1.7 and B.1.351 variants to neutralizing antibodies. *Nat Med.* 2021;27(5):917-924. Published online March 26, 2021. doi:10.1038/s41591-021-01318-5

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. doi:10.1056/nejmoa2034577

Wang P, Casner RG, Nair MS, et al. Increased resistance of SARS-CoV-2 variant P.1 to antibody neutralization. *bioRxiv*. Preprint posted online March 2, 2021. doi:10.1101/2021.03.01.433466

Tweet Four

CDC COVID-19 Response Team. Allergic reactions Including anaphylaxis after receipt of the first dose of Moderna COVID-19 vaccine — United States, December 21, 2020–January 10, 2021. *MMWR Morb Mortal Wkly Rep.* 2021;70(4):125-129. doi:10.15585/mmwr.mm7004e1

CDC COVID-19 Response Team. Allergic reactions including anaphylaxis after receipt of the first dose of Pfizer-BioNTech COVID-19 vaccine — United States, December 14–23, 2020. *MMWR Morb Mortal Wkly Rep.* 2021;70(2):46-51. doi:10.15585/mmwr.mm7002e1

Centers for Disease Control and Preventions. Interim clinical considerations for use of COVID-19 vaccines currently approved or authorized in the United States. CDC website. Updated May 14, 2021. Accessed May 20, 2021. https://www.cdc.gov/vaccines/covid-19/info-by-product/clinical-considerations.html#Contraindications

Shimabukuro TT, Cole M, Su JR. Reports of anaphylaxis after receipt of mRNA COVID-19 vaccines in the US—December 14, 2020-January 18, 2021. *JAMA*. 2021;325(11):1101. doi:10.1001/jama.2021.1967

Tweet Five

Gargano JW, Wallace M, Hadler SC, 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 Morb Mortal Wkly Rep. 2021;70:977–982.

Tweet Seven

MacNeil JR, Su JR, Broder KR, et al. Updated recommendations from the advisory committee on immunization practices for use of the Janssen (Johnson & Johnson) COVID-19 vaccine after reports of thrombosis with thrombocytopenia syndrome among vaccine recipients — United States, April 2021. *MMWR Morb Mortal Wkly Rep.* 2021;70(17):651-656. doi:10.15585/mmwr.mm7017e4

Tweet Eight

Shimabukuro TT. Update: Thrombosis with thrombocytopenia syndrome (TTS) following COVID-19 vaccination Advisory Committee on Immunization Practices (ACIP). May 12, 2021. Accessed October 6, 2021. https://www.cdc.gov/vaccines/acip/meetings/downloads/slides-2021-04-23/03-COVID-Shimabukuro-508.pdf

Tweet Nine

Centers for Disease Control and Prevention. Johnson & Johnson's Janssen COVID-19 Vaccine overview and safety. CDC website. Updated May 11, 2021. Accessed May 20, 2021. https://www.cdc.gov/coronavirus/2019-ncov/vaccines/different-vaccines/janssen.html

MacNeil JR, Su JR, Broder KR, et al. Updated recommendations from the Advisory Committee on Immunization Practices for use of the Janssen (Johnson & Johnson) COVID-19 vaccine after reports of thrombosis with thrombocytopenia syndrome among vaccine recipients — United States, April 2021. MMWR Morb Mortal Wkly Rep. 2021;70(17):651-656. doi:10.15585/mmwr.mm7017e4

Oliver SE, Gargano JW, Scobie H, et al. The Advisory Committee on Immunization Practices' interim recommendation for use of Janssen COVID-19 vaccine - United States, February 2021. *MMWR Morb Mortal Wkly Rep.* 2021;70(9):329-332. doi:10.15585/mmwr.mm7009e4

Shinde V, Bhikha S, Hoosain Z, et al. Efficacy of NVX-CoV2373 Covid-19 vaccine against the B.1.351 variant. *N Engl J Med*. 2021;384:1899-1909. doi:10.1056/nejmoa2103055

Tweet Ten

Thompson MG, Burgess JL, Naleway AL, et al. Interim estimates of vaccine effectiveness of BNT162b2 and mRNA-1273 COVID-19 vaccines in preventing SARS-CoV-2 infection among health care personnel, first responders, and other essential and frontline workers — eight U.S. locations, December 2020–March 2021. *MMWR Morb Mortal Wkly Rep.* 2021;70(13):495-500. doi:10.15585/mmwr.mm7013e3

Tweet Eleven

BioNTech SE. Study to evaluate the safety, tolerability, and immunogenicity of an RNA vaccine candidate against COVID-19 in healthy children <12 years of age. ClinicalTrials.gov website. Accessed May 20, 2021. https://clinicaltrials.gov/ct2/show/NCT04816643

Food and Drug Administration. Coronavirus (COVID-19) update: FDA authorizes Pfizer-BioNTech COVID-19 vaccine for emergency use in adolescents in another important action in fight against pandemic. FDA website. May 10, 2021. Accessed May 23, 2021. https://www.fda.gov/news-events/press-announcements/coronavirus-covid-19-update-fda-authorizes-pfizer-biontech-covid-19-vaccine-emergency-use

Moderna Inc. Moderna announces TeenCOVE study of its COVID-19 vaccine in adolescents meets primary endpoint and plans to submit data to regulators in early June. Moderna website. May 25 2021. Accessed May 25, 2021. https://investors.modernatx.com/news-releases/news-release-details/moderna-announces-teencove-study-its-covid-19-vaccine

ModernaTX, Inc. A study to evaluate safety and effectiveness of mRNA-1273 COVID-19 vaccine in healthy children between 6 months of age and less than 12 years of age. ClinicalTrials.gov website. Accessed May 20, 2021. https://clinicaltrials.gov/ct2/show/NCT04796896

Novavax, Inc. Novavax initiates pediatric expansion for phase 3 clinical trial of COVID-19 vaccine. Novavax website. May 3 2021. Accessed May 25, 2021. https://ir.novavax.com/2021-05-03-Novavax-Initiates-Pediatric-Expansion-for-Phase-3-Clinical-Trial-of-COVID-19-Vaccine

Tweet Twelve

Brown, CM, Vostok J, Johnson H, et al. Outbreak SARS-CoV-2 infections, including COVID-19 vaccine breakthrough infections, associated with large public gatherings – Barnstable County, Massachusetts, July 2021. *MMWR Morb Mortal Wkly Rep.* 2021;70(31):1059-1062.

Levine-Tiefenbrun M, Yelin I, Katz R, et al. Initial report of decreased SARS-CoV-2 viral load after inoculation with the BNT162b2 vaccine. *Nat Med.* 2021;27:790–792. https://doi.org/10.1038/s41591-021-01316-7

Tweet Thirteen

Barouch DH, Stephenson KE, Sadoff J, et al. Durable humoral and cellular immune responses 8 months after Ad25.COV2.S vaccination. *N Engl J Med*. 2021;385:951-953.

Doria-Rose N, Suthar MS, Makowski M, et al. Antibody persistence through 6 months after the second dose of mRNA-1273 vaccine for Covid-19. *N Engl J Med*. 2021;384:2259-2261. doi:10.1056/nejmc2103916

Mahase E. Covid-19: Pfizer vaccine's efficacy decline from 96% to 84% four months after second dose, company reports. *BMJ*. 2021;377:n1920. doi:10.1136/bmj.n1920

Pfizer Inc. Pfizer and Biontech confirm high efficacy and no serious safety concerns through up to six months following second dose in updated topline analysis of landmark COVID-19 vaccine study. Pfizer website. April 1, 2021. Accessed April 14, 2021. https://www.pfizer.com/news/press-release/press-release-detail/pfizer-and-biontech-confirm-high-efficacy-and-no-serious

Tweet Fourteen

Barouch DH, Stephenson KE, Sadoff J, et al. Durable humoral and cellular immune responses 8 months after Ad25.COV2.S vaccination. *N Engl J Med*. 2021;385:951-953.

Bar-On YM, Goldberg Y, Mandel M, et al. Protection of BNT162b2 vaccine booster against Covid-19 in Israel. *N Engl J Med*. 2021. doi:10.1056/NEJMoa2114255

Choi A, Koch M, Wu K, et al. Safety and immunogenicity of SARS-CoV-2 variant m RNA vaccine boosters in healthy adults: an interim analysis. *Nat Med*. 2021. doi:10.1038/s41591-021-01527-y

Tweet Fifteen

Centers for Disease Control and Prevention. Who Is Eligible for a COVID-19 Vaccine Booster Shot? CDC website. September 30, 2021. Accessed October 6, 2021. https://www.cdc.gov/coronavirus/2019-ncov/vaccines/booster-shot.html

Food and Drug Administration. Coronavirus (COVID-19) Update: FDA Authorizes Additional Vaccine Dose for Certain Immunocompromised Individuals. FDA website. August 12, 2021. Accessed October 6, 2021. https://www.fda.gov/news-events/press-announcements/coronavirus-covid-19-update-fda-authorizes-additional-vaccine-dose-certain-immunocompromised

Food and Drug Administration. FDA Authorizes Booster Dose of Pfizer-BioNTech COVID-19 Vaccine for Certain Populations. FDA website. September 22, 2021. Accessed October 6, 2021. https://www.fda.gov/news-events/press-announcements/fda-authorizes-booster-dose-pfizer-biontech-covid-19-vaccine-certain-populations

Kamar N, Abravanel F, Marion O, Couat C, Izopet J, Del Bell A. Three doses of an mRNA Covid-19 vaccine in solid-organ transplant recipients. *N Engl J Med*. 2021;385(7):661-662. doi:10.1056/NEJMc2108861

Tweet Sixteen

Goel RR, Apostolidis SA, Painter MM, et al. Distinct antibody and memory B cell responses in SARS-CoV-2 naïve and recovered individuals following mRNA vaccination. *Sci Immunol.* 2021;6(58). doi:10.1126/sciimmunol.abi6950

Food and Drug Administration. Coronavirus (COVID-19) update: FDA authorizes additional vaccine dose for certain immunocompromised individuals. FDA website. August 12, 2021. https://www.fda.gov/news-events/press-announcements/coronavirus-covid-19-update-fda-authorizes-additional-vaccine-dose-certain-immunocompromised

Tweet Eighteen

Collier AY, McMahan K, Yu J, et al. Immunogenicity of COVID-19 mRNA vaccines in pregnant and lactating women. *JAMA*. 2021;325(23):2370-2380. Published online May 13, 2021. doi:10.1001/jama.2021.7563

Gray KJ, Bordt EA, Atyeo C, et al. Coronavirus disease 2019 vaccine response in pregnant and lactating women: a cohort study. *Am J Obstet Gynecol*. 2021;225(3):P303.e1-303.e17. doi:10.1016/j.ajog.2021.03.023

Glossary

Abs, antibodies

b/f, before

bc, because

COVID-19, coronavirus disease 2019

CDC, Centers for Disease Control and Prevention

Ct, cycle threshold

CVST, cerebral venous sinus thrombosis

d, day(s)

Est, estimated

EUA, emergency use authorization

FDA, Food and Drug Administration

HCP, healthcare provider

HTN, hypertension

IgG, Immunoglobulin G

IM, intramuscular

m, month(s)

MMWR, Morbidity and Mortality Weekly Report

mRNA, messenger ribonucleic acid

NIH, National Institutes of Health

NT50, SARS-CoV-2 neutralization titers

PBO, placebo

Ph, phase

RBD, receptor-binding domain

RCT, randomized controlled trial

RWE, real-world evidence

SAE, serious adverse event

SARS-CoV-2, severe acute respiratory syndrome coronavirus 2

TTS, thrombosis with thrombocytopenia syndrome

VOC, variant of concern

VOI, variant of interest

w, week(s)

w/, with

Y, year(s)

YO, years-old

YOA, years of age