

Risk Mitigation for COVID-19: A Medical “Least Restrictive Means” Analysis Tool

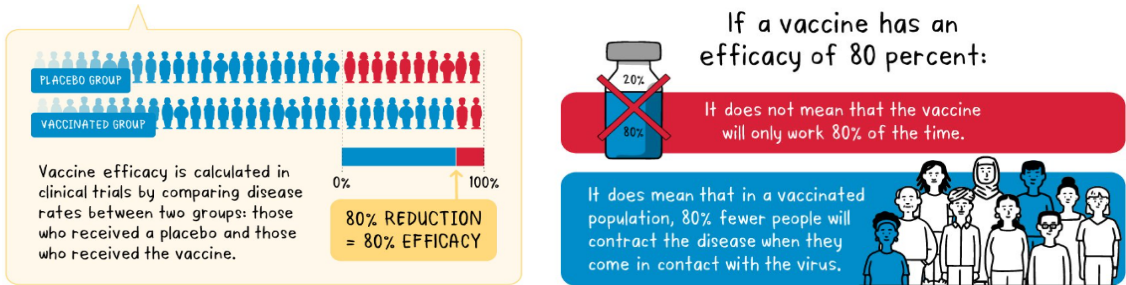
Under the Religious Freedom Restoration Act of 1993 (RFRA), the Federal Government may not burden an individual’s religion unless the requirement furthers a compelling government interest with the least restrictive means.¹ The military applies RFRA through DoD Instruction (DoDI) 1300.17, Religious Liberty in the Military Services, September 1, 2020. It is DoD policy to accommodate religious practices “which do not have an adverse impact on military readiness, unit cohesion, good order and discipline, or health and safety.”² DAFI 52-201 notes that if a compelling governmental interest exists, the government must consider whether vaccination is the least restrictive means necessary to achieve the compelling interest. This DAFI defines the least restrictive means as “an individualized determination that, in realizing its compelling interest, the government could not have employed means that were less burdensome on the military member’s religious liberties.”³ Therefore, it is very important for the MAJCOM/FLDCOM/FOA/DRUs, legal teams, and the AF/SG, as the appellate authority, to understand if preventive measure(s) would be as effective as vaccination (with other continued mitigation strategies) in furthering the compelling government interest.

*****This data pre-dates the Omicron variant which will impact transmissibility and outcomes.*****

*****Adequate data is lacking for the effectiveness of combinations of mitigation strategies.*****

How effective is vaccination at preventing COVID-19 transmission?

COVID-19 vaccination effectiveness against symptomatic infection varies according to type of study, length of time since completing vaccine series, and predominant variant in circulation. Vaccine efficacy (vaccine performance in clinical trials⁴) against infection with mRNA vaccines in clinical trials is 91-93% at 6 months after primary series;^{5,6} however, observation studies may indicate lower vaccine effectiveness (vaccine performance in non-ideal conditions/in the population).



¹ 42 U.S.C. §2000bb, *et seq.* The Religious Land Use and Institutionalized Persons Act of 2000 (RLUIPA), 42 U.S.C. §2000cc, *et seq.*, amended RFRA to cover “any exercise of religion, whether or not compelled by, or central to, a system of religious belief.”

² DoDI 1300.17, para. 1.2b

³ DAFI 52-201, para. 1.1.

⁴ World Health Organization. Vaccine Efficacy, Effectiveness and Protection. *World Health Organization*. Published 14 Jul 21. <https://www.who.int/news-room/feature-stories/detail/vaccine-efficacy-effectiveness-and-protection>

⁵ Thomas, Stephen J., et al. "Safety and efficacy of the BNT162b2 mRNA Covid-19 vaccine through 6 months." *New England Journal of Medicine* 385.19 (2021): 1761-1773.

⁶ <https://investors.modernatx.com/news/news-details/2021/Moderna-Completes-Submission-of-Biologics-License-Application-to-the-U-S-Food-and-Drug-Administration-for-its-COVID-19-Vaccine-08-25-2021/default.aspx>

⁷ World Health Organization. Vaccine Efficacy, Effectiveness and Protection. *World Health Organization*. Published 14 Jul 21. <https://www.who.int/news-room/feature-stories/detail/vaccine-efficacy-effectiveness-and-protection>

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As of November 2021, vaccine effectiveness for COVID-19 vaccines (mRNA and Adenoviral vector vaccines) was 50-82% effective at preventing initial infection (or having a positive test).^{8,9} Vaccinated members also clear the virus days faster (average 3-6 days for those fully vaccinated vs. 13-18 days with Delta) and therefore are contagious for less days than those unvaccinated.^{10 11 12} Transmission of COVID-19 can occur in vaccinated individuals (secondary attack rate for Delta of 25% with prolonged, close contacts)¹³, but personnel are much less likely to develop severe disease, be hospitalized, or die as a result of being vaccinated.^{14 15} With Delta, those fully-vaccinated had a 5-fold decreased risk of infection, a 10-fold decreased risk of hospitalization, and a 10-fold decreased risk of death.¹⁶

Estimated COVID-19 outcomes prevented per 100,000 persons during 120 days after 2-dose mRNA COVID-19 vaccination by sex and age group – U.S. 2021¹⁷

	Benefits: COVID-19 Outcomes Prevented After 2-dose mRNA COVID-19 vaccine series				Harms: Adverse Effects
Age Group (yrs)	Cases	Hospitalizations	ICU Admissions	Deaths	Myocarditis
FEMALES					
18-29	12,800	750	50	5	3-4
30-49	14,600	950	140	20	1-2
50-64	17,500	1,700	375	125	1

⁸ Office for National Statistics. Coronavirus (COVID-19) Infection Survey Technical Article: Impact of Vaccination on Testing Positive in the UK: October 2021. <https://www.ons.gov.uk/peoplepopulationandcommunity/healthandsocialcare/conditionsanddiseases/articles/coronaviruscovid19infectionsurveytechnicalarticleimpactofvaccinationontestingpositiveintheuk/latest>

⁹ Oliver A. Updates to the Evidence to Recommendation Framework: Pfizer-BioNTech and Moderna COVID-19 Vaccine Booster Doses. *Centers for Disease Control and Prevention*. Published 19 Nov 21. <https://www.cdc.gov/vaccines/acip/meetings/downloads/slides-2021-11-19/06-COVID-Oliver-508.pdf>

¹⁰ Singanayagam, A., et al. "Community transmission and viral load kinetics of the SARS-CoV-2 delta (B. 1.617. 2) variant in vaccinated and unvaccinated individuals in the UK: a prospective, longitudinal, cohort study." *The Lancet Infectious Diseases* (2021).

¹¹ Chia, PY., et al. Virological and serological kinetics of SARS-CoV-2 delta variant vaccine-breakthrough infections: a multi-center cohort study. *medRxiv* 2021; published online 31 Jul 21. <https://doi.org/10.1101/2021.07.28.21261295> (preprint).

¹² Kissler, SM., et al. Viral Dynamics of SARS-CoV-2 Variants in Vaccinated and Unvaccinated Individuals. *medRxiv* 2021; published online 25 Aug 21. <https://doi.org/10.1101/2021.02.16.21251535>

¹³ Singanayagam, Anika, et al. "Community transmission and viral load kinetics of the SARS-CoV-2 delta (B. 1.617. 2) variant in vaccinated and unvaccinated individuals in the UK: a prospective, longitudinal, cohort study." *The Lancet Infectious Diseases* (2021).

¹⁴ Centers for Disease Control and Prevention. The Possibility of COVID-19 After Vaccination: Breakthrough Infections. *Centers for Disease Control and Prevention*. Published 9 Nov 21. <https://www.cdc.gov/coronavirus/2019-ncov/vaccines/effectiveness/why-measure-effectiveness/breakthrough-cases.html>

¹⁵ Tenforde, Mark W., et al. "Association Between mRNA Vaccination and COVID-19 Hospitalization and Disease Severity." *JAMA* (2021).

¹⁶ Centers for Disease Control and Prevention. Monitoring Incidence of COVID-19 Cases, Hospitalizations, and Deaths, by Vaccination Status—13 U.S. Jurisdictions, April 4-July 17, 2021. *MMWR. Morbidity and Mortality Weekly Report*, 70(37); 1284-1290.

¹⁷ Rosenblum HG, et al. (2021) Use of COVID-19 Vaccines After Reports of Adverse Events Among Adult Recipients of Janssen (Johnson & Johnson) and mRNA COVID-19 Vaccines (Pfizer-BioNTech and Moderna): Update from the Advisory Committee on Immunization Practices — United States, July 2021. *MMWR Morb Mortal Wkly Rep* 2021;70:1094-1099. <http://dx.doi.org/10.15585/mmwr.mm7032e4>

MALES					
18-29	9,600	300	60	3	22-27
30-49	11,000	700	160	25	5-6
50-64	14,700	1,900	500	150	1
≥65	52,700	12,500	3,500	2,400	1

How effective is mask wear by itself at preventing COVID-19 transmission? What about non-medical personnel using N-95 masks?

Cloth face coverings and surgical masks provide source control (reduction of virus shed by someone infected) and personal protection (filtering out of virus for the mask wearer) against small inhalable infectious particles. As source control, consistent and correct wear of multiple-layered cloth masks filter out 50-70% of viral particles and limit the distance of spread for the remaining virus. For the wearer, consistent and correct wear of a multiple-layered cloth mask can filter out up to 50% of viral particles. When near others, many people do not constantly wear their mask and when wearing it, many do not wear a clean (or new) mask daily with a snug fit (no gaps) over the mouth and nose. Even when worn consistently and correctly, extended durations in close contact with an infectious person can still lead to transmission. Data suggest that consistent, correct mask wear decreases COVID-19 incidence by 10-79%,¹⁸ but typical use in the general population is not nearly this effective. Mask mandates decrease transmission by 2-29% and mortality by 45.7%.¹⁹

Cloth and surgical masks limit the number of larger respiratory particles in a space, but they do not prevent the emission of most small particles (aerosols) exhaled during breathing, talking, singing, coughing, or other respiratory actions. Most studies show no statistically significant difference in infection rates between surgical and N-95 mask wear. However, in a single study of healthcare workers, consistent surgical mask wear led to a 66% reduction and N-95 mask wear showed an 86% reduction in coronavirus infections (not limited to COVID-19) compared to those unmasked.²⁰ (Of note, healthcare workers are trained on proper use and fit-tested for un-valved, NIOSH-approved N-95 masks to ensure a proper seal. Therefore, this study is not generalizable to public use.)

If both people are wearing a typical cloth mask, the receiver's time to an infectious dose increases by minutes. If both people are wearing a surgical mask, the time to receive an infectious dose increases to an hour. If both people are wearing a non-fit-tested N95, the time to an infectious dose increases to over 6 hours.²¹ Additionally, disease risk associated with mask wearing increases due to variability of human behavior – type of mask worn, how the mask is worn, in what settings it's worn, etc.

¹⁸ Center for Disease Control and Prevention. Science Brief: Community Use of Masks to Control the Spread of SARS-CoV-2. Updated 6 Dec 21. <https://www.cdc.gov/coronavirus/2019-ncov/science/science-briefs/masking-science-sars-cov2.html>

¹⁹ Talic S, et al. Effectiveness of Public Health Measures in Reducing the Incidence of COVID-19, SARS-CoV Transmission, and COVID-19 Mortality: Systematic Review and Meta-Analysis. *British Medical Journal* 2021; 375: e068302. <https://doi.org/10.1136/bmj-2021-068302>

²⁰ Li J, et al. Protective Efficient Comparisons Among All Kinds of Respirators and Masks for Health-Care Workers Against Respiratory Viruses. *Medicine (Baltimore)* 2021: 100(34): e27026. <https://doi.org/10.1097/MD.00000000000027026>.

²¹ Brosseau, LM., et al. Commentary: What Can Masks Do? Part 1: The Science Behind COVID-19 Protection. Published 14 Oct 21. <https://www.cidrap.umn.edu/news-perspective/2021/10/commentary-what-can-masks-do-part-1-science-behind-covid-19-protection>

How effective is vaccination plus mask wear at preventing COVID-19 transmission?

The Centers for Disease Control and Prevention (CDC) note a layered approach is recommended with multiple mitigation strategies (social distancing, mask wearing, hand hygiene, vaccination, etc.). Vaccination provides protection to the individual and others. If a vaccinated person is within 6 feet of an infected person, mask wear adds additional protection which may delay transmission by minutes to hours. Fully vaccinated people, if they become infected with SARS-CoV-2, can transmit the virus for a small amount of time; therefore, wearing a mask is recommended for fully vaccinated persons in settings of substantial or high transmission.

How effective were the military's previous COVID-19 mitigation measures? Could continuation of the measures used since the pandemic started in early 2020 be effective enough?

DoD mitigation measures have included mask wear, hand sanitizer usage, COVID-19 testing, deep cleaning, social distancing, curtailed social gatherings, limited building occupancy, decrease/cessation of travel (TDYs), restriction of movement/quarantine/isolation periods (around leave, TDY, PCS, deployment, exercises, COVID-19 exposure, and COVID-19 infection), limiting exercises, and telework.²² Despite these extensive measures, eleven percent of service members have been infected. The relatively young and healthy US service member population is not immune to long-term complications or deaths related to COVID-19. As of 16 Nov 21, over two thousand service members have been hospitalized for COVID-19 related illness and 75 service members have died.²⁴

How effective is prior infection at preventing COVID-19 transmission?

While evidence of prior infection is considered adequate documentation for some vaccine requirements such as measles, mumps, rubella, varicella (chickenpox), and hepatitis B virus, there are other vaccine preventable pathogens where previous infection does not induce life-long sterilizing immunity, and prior infection is not considered an acceptable medical exemption (influenza, adenovirus).²⁵

Although COVID-19 disease does provide some degree of natural immunity to SARS-CoV-2 virus, the length and completeness of protection varies. Current evidence has not determined an antibody threshold (nor a FDA-authorized or –approved test to assess this) indicative of protection from re-infection. Evidence is also inadequate to associate specific antibody levels with the degree of re-infection risk for an individual.²⁶ 1-10% of people do not develop long lasting (IgG-type) antibodies following confirmed COVID-19 infection (vs. 100% developing antibodies for the mRNA vaccines and 90% for Janssen).^{27 28} Antibody titers peak at 3-5 weeks after infection and then begin to wane.

²² Cancian MF. COVID-19 and the Military: Maintaining Operations While Supporting Civil Society. *Center for Strategic & International Studies*; published 12 Feb 21. <https://www.csis.org/analysis/covid-19-and-military-maintaining-operations-while-supporting-civil-society>

²³ Deputy Chief of Staff for Manpower, Personnel, and Services memorandum, "EXECUTION ORDER Supplement 3 – Reporting Status of Restriction of Movement (ROM) of Personnel in Support of COVID-19," 24 February 2021.

²⁴ Myers M. 21-year-old Soldier's Death Last Year Attributed to COVID-19. *Military Times*; published online 16 Nov 21. <https://www.militarytimes.com/news/pentagon-congress/2021/11/16/21-year-old-soldiers-death-last-year-attributed-to-covid-19/>

²⁵ Defense Health Agency Procedural Instruction, *Guidance for the DoD Influenza Vaccination Program*, 21 Aug 2020

²⁶ Center for Disease Control and Prevention. Science Brief: SARS-CoV-2 Infection-Induced and Vaccine-Induced Immunity. Updated 29 Oct 21. <https://www.cdc.gov/coronavirus/2019-ncov/science/science-briefs/vaccine-induced-immunity.html>

Neutralizing antibodies demonstrate approximately a 50% reduction within 2-3 months and become undetectable in up to 30% of people within 10 months post-infection.²⁹ Mild or asymptomatic COVID-19 infections tend to generate lower antibody levels than those with severe disease.³⁰ Overall, the duration of protection varies depending on disease severity, person's age, antibody assay utilized, and variants of the virus.³¹ After infections with the original SARS-CoV-2 strain, detectable neutralizing antibodies were found in 84% of people for Alpha, 68% for Delta, and 55% for Beta.³²

Both natural and vaccine immunity decrease the risk of re-infection. Studies vary on their conclusions regarding whether the infection rate is equivalent, lower, or higher in those fully-vaccinated compared to those previously-infected. In two studies, prior infection (without subsequent vaccination) was associated with 2.3 times the odds of reinfection and 5.49 times the rate of hospitalization with re-infection compared with being fully vaccinated.^{33 34} In contrast, another study showed that at six months from vaccination or infection, the rate of infection was 13-fold higher for those vaccinated without prior infection than those with prior infection.³⁵ This study makes a good case for vaccine boosters and shows the benefit of vaccination for those previously infected. Vaccination provides a strong boost in protection for people who have recovered from COVID-19, resulting in a 1.85-2.34 fold decreased risk of re-infection.^{36 37 38} Overall, boosting the immune system with a vaccine after infection or initial vaccine series is effective for decreasing the risk of subsequent infection.

How effective is weekly testing at detecting COVID-19 cases (thus indirectly preventing future transmissions)?

²⁷ World Health Organization. (2021) COVID-19 Natural Immunity: Scientific Brief. *World Health Organization* <https://apps.who.int/iris/handle/10665/341241>

²⁸ Center for Disease Control and Prevention. Science Brief: SARS-CoV-2 Infection-Induced and Vaccine-Induced Immunity. Updated 29 Oct 21. <https://www.cdc.gov/coronavirus/2019-ncov/science/science-briefs/vaccine-induced-immunity.html>

²⁹ Center for Disease Control and Prevention. Science Brief: SARS-CoV-2 Infection-Induced and Vaccine-Induced Immunity. Updated 29 Oct 21. <https://www.cdc.gov/coronavirus/2019-ncov/science/science-briefs/vaccine-induced-immunity.html>

³⁰ Long, Q.X., Tang, X.J., Shi, Q.L., Li, Q., Deng, H.J., Yuan, J., Hu, J.L., Xu, W., Zhang, Y., Lv, F.J., et al. (2020). Clinical and immunological assessment of asymptomatic SARS-CoV-2 infections. *Nat. Med.* 26, 1200-1204.

³¹ World Health Organization. (2021) COVID-19 Natural Immunity: Scientific Brief. *World Health Organization* <https://apps.who.int/iris/handle/10665/341241>

³² Center for Disease Control and Prevention. Science Brief: SARS-CoV-2 Infection-Induced and Vaccine-Induced Immunity. Updated 29 Oct 21. <https://www.cdc.gov/coronavirus/2019-ncov/science/science-briefs/vaccine-induced-immunity.html>

³³ Cavanaugh, A. M. (2021). Reduced Risk of Reinfection with SARS-CoV-2 After COVID-19 Vaccination—Kentucky, May–June 2021. *MMWR. Morbidity and Mortality Weekly Report*, 70.

³⁴ Bozio CH., et al. Laboratory-Confirmed COVID-19 Among Adults Hospitalized with COVID-19-Like Illness with Infection-Induced or mRNA Vaccine-Induced SARS-CoV-2 Immunity—Nine States, January–September 2021. *MMWR. Morbidity and Mortality Weekly Report*, 70.

³⁵ Gazit S., et al. (2021). Comparing SARS-CoV-2 Natural Immunity to Vaccine-Induced Immunity: Reinfections Versus Breakthrough Infections. <https://doi.org/10.1101/2021.08.24.21262415>

³⁶ Cavanaugh, A. M. (2021). Reduced Risk of Reinfection with SARS-CoV-2 After COVID-19 Vaccination—Kentucky, May–June 2021. *MMWR. Morbidity and Mortality Weekly Report*, 70.

³⁷ Stamatatos L., et al. (2021) mRNA Vaccination Boosts Cross-Variant Neutralizing Antibodies Elicited by SARS-CoV-2 Infection. *Science* 372 (6549): 1413-1418. <https://doi.org/10.1126/science.abg9175>

³⁸ Gazit S., et al. (2021). Comparing SARS-CoV-2 Natural Immunity to Vaccine-Induced Immunity: Reinfections Versus Breakthrough Infections. <https://doi.org/10.1101/2021.08.24.21262415>

Antigen tests have a 52.5% chance in those asymptomatic and a 76.7% chance in those symptomatic to identify people with COVID-19. With twice weekly testing, the sensitivity increased to 76.3% without regards to symptoms, to 83.8% within the first week of symptoms, and 95.8% for those with a high viral load. As most should be asymptomatic for the required weekly testing, the chance to identify a member that is actually infected is a little better than 50% with a single antigen test.³⁹

Most Instructions for antigen tests direct at least twice a week, serial testing followed by confirmatory testing (PCR test) in case of a positive antigen test. This is secondary to the risk of false positive and false negative results, especially for asymptomatic individuals. Research indicates testing with an antigen test at least every three days increases the probability of detecting a true positive to a level closer to a weekly PCR test (98.7% accuracy), but detection may not be prior to infectivity. For example, serial antigen testing at least every three days detected true positives with a 95.9% accuracy within a 14 day period from infection. The rate of antigen test detection prior to the first day of infectivity is 37.5%. On the day of peak infectivity viral detection is only 90%.⁴⁰

Overall, serial antigen testing of asymptomatic members will detect most infections, but the member will likely be infectious prior to the test becoming positive. Serial testing will curtail the exposure in the unit after the infection is detected, but this is not as effective as preventing the original infection.

How effective is social distancing (e.g., physical spacing) from others for COVID-19 transmission?

Effectiveness of social distancing depends on the specific activity being conducted (sitting quietly vs forcible singing). A systematic review of physical distancing of at least 3 feet to prevent SARS-CoV-2 transmission demonstrated a 25% reduction in transmission.⁴¹ Although infections through inhalation at distances greater than three to six feet from an infectious source are less likely than at closer distances, the phenomenon has been repeatedly documented under certain preventable circumstances.^{42 43 44} These transmission events have involved the presence of an infectious person exhaling virus indoors for an extended time (more than 15 minutes and in some cases hours) leading to virus concentrations in the air space sufficient to transmit infections to people more than 6 feet away, and in some cases to people who have passed through that space soon after the infectious person left.

How effective is working outside at preventing transmission?

³⁹ Brummer LE., et al., (2021) Accuracy of Novel Antigen Rapid Diagnostics for SARS-CoV-2: A Living Systematic Review and Meta-Analysis. *PLOS Medicine* 18(8): e1003735. <https://doi.org/10.1371/journal.pmed.1003735>

⁴⁰ Smith, Rebecca L., et al. "Longitudinal assessment of diagnostic test performance over the course of acute SARS-CoV-2 infection." *medRxiv* (2021).

⁴¹ Talic S, et al. Effectiveness of Public Health Measures in Reducing the Incidence of COVID-19, SARS-CoV Transmission, and COVID-19 Mortality: Systematic Review and Meta-Analysis. *British Medical Journal* 2021; 375: e068302. <https://doi.org/10.1136/bmj-2021-068302>

⁴² Lendacki FR, Teran RA, Gretsich S, Fricchione MJ, Kerins JL. COVID-19 Outbreak Among Attendees of an Exercise Facility — Chicago, Illinois, August–September 2020. *MMW*

⁴³ Katelaris AL, Wells J, Clark P, et al. Epidemiologic Evidence for Airborne Transmission of SARS-CoV-2 during Church Singing, Australia, 2020. *Emerg Infect Dis.* Apr 5 2021;27(6) <https://doi:10.3201/eid2706.210465>.

⁴⁴ Hamner L, Dubbel P, Capron I, et al. High SARS-CoV-2 Attack Rate Following Exposure at a Choir Practice – Skagit County, Washington, March 2020. *MMWR Morb Mortal Wkly Rep.* May 15 2020;69(19):606-610. doi:10.15585/mmwr.mm6919e6

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Working outside and infection transmission depends on various factors like environment, distance, duration of exposure, mask wear, immunization status, population density, and activities involved. However, overall CDC indicates the risk would be minimal except in areas with high COVID-19 cases with crowded settings or for activities involving close contact with others who are unvaccinated.⁴⁵ In a systematic review, the proportion of COVID-19 cases occurring with outdoor transmissions ranged from <1% to up to 5% of cases compared to indoor transmission.⁴⁶ However, even for those who primarily work outside, the “enclosed space” risk may occur when the member goes indoors for restroom breaks, eating, socializing, meetings, or other situations. The “enclosed space” risk applies even for large enclosed spaces, though the risk may decrease to some degree with low occupancy.

How effective is working in an isolated setting to keep an individual safe? How effective is fulltime teleworking at preventing COVID-19 transmission?

US data shows isolation/lock-downs have been associated with a 4.9% to 14-fold decrease in transmission.⁴⁷ Despite working in an isolated environment by fulltime teleworking, an individual still has to interact with others in the local community, family, and friends. Thus, working in an isolated environment removes risk from viral transmission to others at work, but it does not eliminate risk of infection and disease complications to the individual to include long-COVID symptoms, hospitalizations, ICU admissions, and deaths.

⁴⁵ Centers for Disease Control and Prevention. Participate in Outdoor and Indoor Activities. *Centers for Disease Control and Prevention*. Updated 19 Aug 21. <https://www.cdc.gov/coronavirus/2019-ncov/daily-life-coping/outdoor-activities.html>

⁴⁶ Bulfone TE., et al. (2020). Outdoor Transmission of SARS-CoV-2 and Other Respiratory Viruses, A Systemic Review. *Journal of Infectious Disease*. <https://doi.org/10.1093/infdis/jiaa742>

⁴⁷ Talic S, et al. Effectiveness of Public Health Measures in Reducing the Incidence of COVID-19, SARS-CoV Transmission, and COVID-19 Mortality: Systematic Review and Meta-Analysis. *British Medical Journal* 2021; 375: e068302. <https://doi.org/10.1136/bmj-2021-068302>