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# Association of Country-wide Coronavirus Mortality with Demographics, Testing, Lockdowns, and Public Wearing of Masks

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Abstract. We studied sources of variation between countries in per-capita mortality from COVID-19 (caused by the SARS-CoV-2 virus). Potential predictors of per-capita coronavirus-related mortality in 200 countries by May 9, 2020 were examined, including age, gender, obesity prevalence, temperature, urbanization, smoking, duration of the outbreak, lockdowns, viral testing, contact-tracing policies, and public mask-wearing norms and policies. Multivariable linear regression analysis was performed. In univariate analysis, the prevalence of smoking, per-capita gross domestic product, urbanization, and colder average country temperature were positively associated with coronavirus-related mortality. In a multivariable analysis of 196 countries, the duration of the outbreak in the country, and the proportion of the population aged 60 years or older were positively associated with per-capita mortality, whereas duration of mask-wearing by the public was negatively associated with mortality (all P < 0.001). Obesity and less stringent international travel restrictions were independently associated with mortality in a model which controlled for testing policy. Viral testing policies and levels were not associated with mortality. Internal lockdown was associated with a nonsignificant 2.4% reduction in mortality each week (P = 0.83). The association of contact-tracing policy with mortality was not statistically significant (P = 0.06). In countries with cultural norms or government policies supporting public mask-wearing, per-capita coronavirus mortality increased on average by just 16.2% each week, as compared with 61.9% each week in remaining countries. Societal norms and government policies supporting the wearing of masks by the public, as well as international travel controls, are independently associated with lower per-capita mortality from COVID-19.

## INTRODUCTION

The COVID-19 global pandemic caused by infection with SARS-CoV-2 has presented a major public health challenge. For reasons that are not completely understood, the percapita mortality from COVID-19 varies by several orders of magnitude between countries. Numerous sources of heterogeneity have been hypothesized. Higher mortality has been observed in older populations and in men. Patient-level behaviors, such as smoking, might also have an impact. Other potentially relevant factors include economic activity, and environmental variation, such as temperature. More urban settings and increased population density would be expected to enhance viral transmission.

In addition, public health responses to the COVID-19 pandemic may influence per-capita mortality. Various strategies have been implemented, ranging from robust testing programs to lockdown or stay-at-home orders, to mandates regarding social distancing and face mask usage. Practices with theoretical benefit, such as social distancing, stay-at-home orders, and implementation of mandates regarding use of masks in public spaces, must be assessed quickly, as implementation has the potential to reduce morbidity and mortality.

Mask usage by the public is postulated to decrease infection by blocking the spread of respiratory droplets,<sup>1</sup> and was successfully implemented during other coronavirus outbreaks (i.e., SARS and Middle East Respiratory Syndrome).<sup>6</sup> In the context of the ongoing pandemic, we assessed the impact

of masks on per-capita COVID-19–related mortality, controlling for the aforementioned factors. We hypothesized that in countries where mask use was either an accepted cultural norm or favored by government policies on a national level, the per-capita mortality might be reduced, as compared with countries which did not advocate masks.

## **METHODS**

**Data acquisition.** To be included in the study, countries had to 1) have coronavirus mortality data listed in the publicly available Worldometer database on May 9, 2020<sup>7</sup>; 2) have dates of first case and first death reported by the European CDC (which did tabulate worldwide data)<sup>8</sup>; and 3) have an assessment of viral testing through May 9, 2020 by either 3a) report on Worldometer of numbers of coronavirus PCR tests performed<sup>7</sup> or 3b) testing and lockdown policies graded by the University of Oxford coronavirus government response tracker.<sup>9,10</sup>

Oxford University defined and scored several composite government response indices. The stringency index was defined in terms of containment policy and public information. The government response index incorporated containment, economic measures, public information, and testing and tracing policies. The containment and health index was defined in terms of containment measures, public information, and testing and tracing policies.

Archived viral testing data tabulated by Worldometer for April 2020 were also downloaded from the Internet Archive. <sup>11</sup> Mean temperature in each country for each day of its outbreak, from the start of that country's outbreak through April 16, 2020, was estimated using the average monthly temperature in the country's largest city from public sources. <sup>12,13</sup>

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Online news reports and government statements, including those cited by a previous review<sup>14</sup> and a public database,<sup>15</sup> were searched to identify countries in which the public wore masks early in the outbreak based on tradition,<sup>16–18</sup> as well as countries in which the national government mandated or recommended mask-wearing by the public before April 16, 2020.

For each country, the population, <sup>19</sup> fraction of the population aged 60 years and older<sup>20</sup> and those aged 14 years and younger, <sup>20</sup> male: female ratio per country, <sup>20</sup> surface area, <sup>19,20</sup> gross domestic product per capita, <sup>21</sup> percent urbanization, <sup>19,22</sup> prevalence of current smoking among adults, <sup>23–26</sup> and prevalence of adult obesity <sup>27–46</sup> were tabulated. Obesity was defined as a body mass index of 30 kg/m<sup>2</sup>. <sup>27–46</sup> Urbanization is the fraction of the population living in an urban area. <sup>47</sup> Whether a nation was an isolated political entity on an island was also recorded.

**Statistical analysis.** The prevalence of an infectious process undergoing exponential growth (or decay) appears linear over time when graphed on a logarithmic scale. Therefore, we postulated that the logarithm of the country-wide infection prevalence would be linearly related with the duration of the outbreak in each country, as defined in the following paragraph. In addition, our analysis postulated that deaths from coronavirus would follow infections with some delay.

On average, the time from infection with the coronavirus to onset of symptoms is 5.1 days, <sup>48</sup> and the time from symptom onset to death is on average 17.8 days. <sup>49</sup> Therefore, the time from infection to death is expected to be 23 days. <sup>1,50</sup> These incubation and mortality times were prespecified. <sup>1,50</sup> Therefore, the date of each country's initial infection was estimated as the earlier of 5 days before the first reported infection, or 23 days before the first death. <sup>8,11,51</sup> Deaths by May 9, 2020 would typically reflect infections beginning 23 days previously (by April 16). Therefore, we recorded the time from the first infection in a country until April 16. To summarize, the duration of the outbreak in the country was defined as the time from the estimated date of first infection (the earlier of 5 days before the first reported case or 23 days before the first death) until April 16.

We also recorded the period of the outbreak: 1) from when public mask-wearing was recommended until April 16, 2) from the mandating of international travel restrictions or quarantine until April 16, and 3) from the start of mandated limits on internal activities (i.e., lockdowns, defined as any closure of schools or workplaces, limits on public gatherings or internal movement, or stay-at-home orders) until April 16. For countries scored by Oxford University, the Oxford data were used to determine the start of international travel restrictions and lockdowns on internal activity. In addition, we calculated the mean time-weighted score for each lockdown and testing policy as graded by the University of Oxford for the duration of the country's outbreak, from beginning through April 16.9 For instance, if the school closure score was one for half the country's outbreak and two for the other half, then the mean score was 1.5.

Per-capita mortality can be analyzed as a binary outcome (low or high), or as a continuous variable. Each approach has strengths and weaknesses. Analysis of a binary outcome is not unduly influenced by outliers. Countries with extremely low or high mortality are included in the appropriate group, but the exact mortality value does not change the results.

Moreover, analysis of a binary outcome facilitates clear communication because one can describe the characteristics of low and high mortality countries. We used the median value as the threshold to separate countries with low and high percapita mortality.

On the other hand, per-capita mortality is in fact a continuous variable, and the separation of countries less than or greater than a threshold value is somewhat arbitrary, or susceptible to chance variation. Analysis of mortality as a continuous variable uses all the information available, and can appropriately model the exponential growth of an infection. We view the binary and continuous analyses as complementary. When one sees that a univariate association is found with both types of analyses, one gains confidence that the association is not an artifact of the analytic method selected.

In univariate analysis, characteristics of countries with percapita mortality above the median value ("high-mortality" countries) were compared with the remaining ("low-mortality") countries by the two-sample *t*-test using groups.

Significant predictors of per-capita coronavirus mortality in the univariate analysis were analyzed by stepwise backward multivariable linear regression analysis. The dependent variable was the logarithm (base 10) of per-capita coronavirusrelated mortality. Because of the importance relative to public health, the weeks the country spent in lockdown, with international travel restrictions, and using masks, and percapita testing levels, were retained in the model. In addition, because of their biological plausibility and presumed importance, urbanization, prevalence of obesity, and average ambient temperature were retained in most of the multivariable models presented in the following text. Statistical analysis was performed with XLSTAT 2020.1 (Addinsoft, New York, NY). An alpha (P-value) of 0.05 was deemed to be statistically significant. The study was approved by the Virginia Commonwealth University Office of Research Subjects Protection.

## **RESULTS**

We studied coronavirus mortality in 200 countries, of which 183 had testing data, <sup>7</sup> 169 had government policies scored by Oxford University, <sup>9</sup> and 152 fell into both categories.

The 100 lower-mortality countries had 0.99 deaths per million population, in contrast with an average of 93.3 deaths per million population in the 100 higher-mortality countries (P < 0.001, Table 1, Supplemental Table A1). The median value was 3.6 deaths per million population. The same independent variables were found to be statistically significant on univariate analysis, regardless of whether per-capita mortality was considered a binary or continuous variable, as outlined in the following text (Table 1, Supplemental Table A3).

We found that 19 of 100 low-mortality countries were isolated on islands, compared with 28 of 100 high-mortality countries (P = 0.18). Country surface area and population were not associated with coronavirus mortality (Table 1).

**Population characteristics.** Countries with a higher fraction of the population older than 60 years suffered higher coronavirus mortality. Countries with low mortality had on average 8.8% of their population older than 60 years, as compared with 18.2% in the high-mortality countries (P < 0.001, Table 1). The proportion of the population which was male was not associated with country-wide mortality (P = 0.001).

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TABLE 1

Characteristics of countries with low and high per-capita coronavirus mortality by May 9, 2020 in 200 countries

	Mean (SD)			
	Low mortality	High mortality	P-value	
Deaths (per million)	0.99 (1.14)	93.3 (182.7)	< 0.001	
Deaths (per capita, log)	-6.47 (0.75)	-4.55 (0.64)	< 0.001	
Duration outbreak (weeks)	6.51 (2.87)	7.84 (2.31)	< 0.001	
Duration outbreak without masks (weeks)	4.74 (2.33)	6.69 (2.34)	< 0.001	
Time without international travel restrictions (weeks).	1.44 (1.96)	2.62 (2.38)	< 0.001	
Duration outbreak without internal lockdown (weeks)	1.79 (1.85)	2.83 (2.08)	< 0.001	
Temperature, mean (C)	22.2 (7.6)	14.1 (9.1)	< 0.001	
Urban population (%)	51.5 (22.6)	70.4 (20.0)	< 0.001	
GDP per capita (\$)	9,060 (16,960)	27,140 (27,500)	< 0.001	
Age 14 years and younger (% of population)	32.4 (9.8)	20.2 (6.6)	< 0.001	
Age 60 and older (% of population)	8.8 (5.3)	18.2 (7.9)	< 0.001	
Surface area (km², log)	4.97 (1.19)	4.62 (1.36)	0.06	
Population (log)	6.81 (1.02)	6.61 (1.05)	0.17	
Prevalence males (%)	50.1 (2.1)	50.2 (4.2)	0.95	
Smoking prevalence, adult (%)	13.7 (7.9)	18.4 (7.7)	< 0.001	
Obesity prevalence, adult (%)	14.6 (9.0)	24.0 (7.3)	< 0.001	
Tests per cap. (log) by April 4	-3.73 (1.20)	-2.65 (0.76)	< 0.001	
Tests per cap. (log) by April 16	-3.09 (0.87)	-2.31 (0.67)	< 0.001	
Tests per cap. (log) by May 9	-2.76 (0.86)	-1.92 (0.62)	< 0.001	

GDP = gross domestic product. Durations run from the estimated date of first infection in the country until 23 days before May 9, 2020 (i.e., April 16), or the stated event (mask recommendation or lockdown). Obesity data were available for 196 countries. Testing data were available for 135 countries by April 4, 162 countries by April 16, and 183 countries by May 9.

0.95, Table 1). Smoking prevalence was on average 13.7% in low-mortality countries and 18.4% in high-mortality countries (P < 0.001, Table 1). The prevalence of obesity was on average 14.6% in low-mortality countries and 24.0% in high-mortality countries (P < 0.001, Table 1).

**Temperature.** Colder countries were associated with higher coronavirus mortality in univariate analysis. The mean temperature was 22.2 C (SD 7.6 C) in the low-mortality countries and 14.1 C (SD 9.1 C) in the high-mortality countries (P < 0.001, Table 1).

**Urbanization.** Urbanization was associated with coronavirus mortality in univariate analysis. In low-mortality countries, on average, 52% of the population was urban, as compared with 70% of the population in the high-mortality countries (P < 0.001, Table 1).

## MASKS: EARLY ADOPTION

The WHO initially advised against widespread mask-wearing by the public, as did the U.S. CDC.<sup>1,16</sup> The WHO reversed course and recommended masks in public on June 5, 2020.<sup>52</sup>

Despite these initial recommendations, a number of countries did favor mask wear by the public early in their outbreak, and such countries experienced low coronavirus-related mortality (Supplemental Tables A1 and A2, Figure 1). 17,53-70 It is likely that in Mongolia and Laos, both of which reported no coronavirus-related mortality by May 9, the public began wearing masks before any cases were confirmed in their countries (Supplemental Table A1). We identified 24 countries with recommendations or cultural norms favoring maskwearing by the public within 20 days of the estimated onset of the country's outbreak, 1 including Japan, the Philippines, Macau, Hong Kong, Sierra Leone, Cambodia, Timor-Leste, Vietnam, Malaysia, Bhutan, Venezuela, Taiwan, Slovakia, St. Kitts and Nevis, South Korea, Indonesia, Brunei, Grenada, Mozambique, Uzbekistan, Thailand, and Malawi (Supplemental

Table A1). The average mortality by May 9 for these 24 early mask-wearing countries was 1.5 per million (SD 2.0). Twenty of the 24 were lower-mortality countries (P = 0.001).

An additional 17 countries recommended public masking within 30 days of the estimated onset of their outbreak: São Tomé and Príncipe, Czechia, Dominica, Bangladesh, Zambia, Chad, Benin, Sudan, El Salvador, Antigua and Barbuda, Myanmar, Bosnia and Herzegovina, Côte d'Ivoire, South Sudan, Kenya, Saint Lucia, and Barbados (Supplemental Table A1). The average mortality by May 9 for this group was 8.5 per million (SD 12.4).

Numerous countries recommended masks during the study exposure period, but more than 30 days after the country's outbreak is estimated to have begun. Public mask wear was widespread in China after January 20 (Supplemental Table A2). 54,55,60,71 The following recommended public masking in March: Kuwait. 14 Nepal. Lithuania, the United Arab Emirates (UAE), Slovenia, Iran, 14 Bulgaria, Ukraine, Austria, the Cayman Islands, and Mauritius (Supplemental Table A2). The following recommended public masking in April (by the 16th): Israel, Germany, Brazil, Cuba, Saint Kitts and Nevis, the United States, Singapore, Turkey, France, Cyprus, Peru, India, Colombia, El Salvador, Malawi, the Ivory Coast, 68 Estonia, Trinidad and Tobago, Canada, Tunisia, Morocco, Honduras, the Dominican Republic, Ecuador, Paraguay, Panama, Jamaica, Poland, Guatemala, Bahrain, Guyana, Uruguay, South Africa, Spain, Ethiopia, Sri Lanka, Guinea, Nigeria, Equatorial Guinea, Finland, Luxembourg, Gabon, and Libya (Supplemental Table A2).

Throughout much of East, South, and Southeast Asia, masks were worn by the public as a preventive measure, rather than a policy implemented after evidence emerged of health system overload (Supplemental Tables A1 and A2). The public sometimes implemented masks before government recommendations were issued. For Nepal, India, and Sri Lanka, we did not score the country as mask-wearing until government recommendations were issued, but there

#### CORONAVIRUS EPIDEMIOLOGY

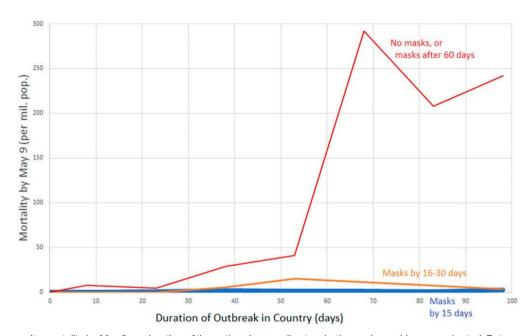


FIGURE 1. Per-capita mortality by May 9 vs. duration of the outbreak according to whether early masking was adopted. Data grouped by whether country did not recommend masks by April 16, 2020 or recommended them more than 60 days after outbreak onset (red line), recommended masks 16–30 days after onset of the country's outbreak (orange line), or recommended masks (or traditionally used masks) within 15 days of the outbreak onset (blue line close to the x-axis). Country mortality was averaged for the following country groups of infection duration: 0–15 days, 16–30 days, 31–45 days, 46–60 days, 61–75 days, 76–90 days, and 91–105 days. For instance, per-capita mortality for all non-mask or late-masking countries with infection duration between 61 and 75 days was averaged, and graphed at the x-value 68 days. Data for graph were derived from 200 countries.

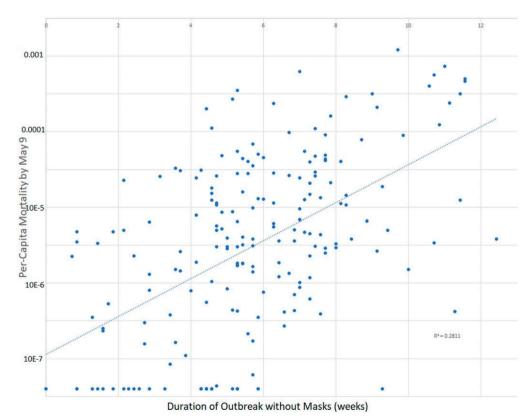


FIGURE 2. Scatterplot of per-capita mortality by May 9, 2020 as a function of the period of the country's outbreak without mask recommendations or norms. The dotted line represents the best fit using least-squares linear regression. Data for graph were derived from 200 countries. The start of the outbreak is defined as 5 days before the first case reported, or 23 days before the first death (whichever was earlier). The duration of the outbreak without masks is defined as the time from the start of the country's outbreak until masks were recommended or until April 16 (whichever came first).

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was evidence of earlier mask wear in public (Supplemental Table A2).

In parts of the Middle East, such as Saudi Arabia and the UAE, masks were embraced by the public even before government requirements (Supplemental Table A2). As noted earlier, 11 African countries recommended or mandated masks within 31 days of the onset of their outbreak (Supplemental Table A1).

Most countries in Europe and North America failed to embrace masks early in their outbreaks and only adopted mask policies after signs of health system overload became apparent. Only three countries in Europe had government recommendations to wear masks within 31 days of the onset of their outbreak: Slovakia, Czechia, and Bosnia and Herzegovina (Supplemental Table A1).

## GRAPHICAL ANALYSIS OF MASK EFFECT

Before the formal statistical analysis, we graphically illustrate the effect of mask wear (Figures 1 and 2). The first figure demonstrates the effect of early mask usage (Figure 1). In the countries not using masks by April 16, or not using them until 60 days after the start of the outbreak, the per-capita mortality by May 9 rises dramatically if the infection has persisted in the country over 60 days (Figure 1, red line). On the other hand, countries in which a mask was used from 16 to 30 days after infection onset had per-capita mortality several orders of magnitude less by May 9 (Figure 1, orange line). When countries recommended masks within 15 days of the onset of the outbreak, the mortality was so low that the curve is difficult to distinguish from the *x*-axis (Figure 1, blue line).

To provide some graphical idea of the scatter of the data when exponential growth is assumed, we graphed per-capita mortality by May 9 on a logarithmic scale as a function of the duration of the country's outbreak not using masks in all 200 countries (Figure 2). This simple model explained 28.1% of the variation in per-capita mortality.

Initial multivariable analysis. An initial multivariable analysis was conducted including all 200 countries. By multivariable linear regression, significant predictors of the logarithm of each country's per-capita coronavirus mortality included duration of the outbreak in the country, duration of wearing masks (P < 0.001), percentage of the population older than 60 years, and urbanization (all  $P \le 0.008$ , Supplemental Table A4). The association of mortality with the timing of international travel restrictions was of borderline statistical significance (P = 0.049). The model explained 48.1% of the variation in percapita mortality (Supplemental Table A4).

Was the association of mask usage with lower mortality an artifact of including countries for which the outbreak had only recently arrived? We repeated the model of Supplemental Table A4 using only the 187 countries for which the outbreak was estimated to have begun at least 60 days before the mortality assessment on May 9 (i.e., by March 17). Once again, masks were significantly associated with lower mortality (P < 0.001). Each week that masks were recommended during the outbreak was associated with an 8.1% increase in per-capita mortality (instead of the 55.7% increase seen each week when masks were not recommended). The prevalence of age older than 60 years (P < 0.001) and urbanization (P = 0.03) were associated with higher per-capita mortality, whereas the time since the

start of international travel restrictions continued to be associated with lower mortality (P = 0.045). Duration of the lockdown (P = 0.83) and temperature (P = 0.99) were not associated with mortality. The model explained 48.7% of the variation in percapita mortality.

We also prepared a multivariable model to predict the logarithm of per-capita coronavirus mortality in the 196 countries with obesity data. In this model, lockdown, obesity, temperature, and urbanization were retained because of their plausibility as important factors (Table 2). By multivariable linear regression, significant predictors of the logarithm of each country's per-capita coronavirus mortality included duration of the outbreak in the country, duration of wearing masks, and percentage of the population older than 60 years (all P < 0.001, Table 2). The associations of obesity and urbanization with increased mortality were not statistically significant (both P = 0.10, Table 2). When controlling for the duration of the outbreak in the country, there appeared to be a negative association between mortality and time in lockdown (P = 0.83) and time with international travel restrictions (P = 0.07), although neither association reached statistical significance (Table 2). The model explained 50.8% of the variation in percapita mortality.

In countries not recommending masks, the per-capita mortality tended to increase each week by a factor of 1.619, or 61.9%. By contrast, in countries recommending masks, the per-capita mortality tended to increase each week by a factor of (1.6193) (0.7174) = 1.162, or just 16.2%. With international travel restrictions in place (without masks), the per-capita mortality increased each week by (1.6193) (0.8634) = 1.398, or 39.8%. Under lockdown (without masks), the per-capita mortality increased each week by (1.6193) (0.9761) = 1.581, or 58.1%, that is, slightly less than the baseline condition (Table 2).

A country with 10% more of its population living in an urban environment than another country tended to suffer mortality 14.8% higher ( $10^{0.0599} = 1.148$ , Table 2). A country in which the percentage of the population aged 60 years or older is 10% higher than in another country tended to suffer mortality 206% higher ( $10^{0.485} = 3.06$ , Table 2). A country with a prevalence of obesity 10% higher tended to suffer mortality 40% higher ( $10^{0.145} = 1.40$ , Table 2).

## NUMBERS OF VIRAL TESTS

Among the 183 countries with viral (PCR) testing data by May 9, per-capita testing performed at all three time points was positively associated with per-capita mortality in univariate analysis (all P < 0.001, Table 1). By May 9, 2020, low-mortality countries had performed one test for every 575 members of the population, whereas high-mortality countries had performed one test for every 83 members of the population (P < 0.001, Table 1).

To the multivariable model (Table 2), we added testing by May 9, using data from 179 countries with both testing and obesity data. Duration of the outbreak in the country, the duration that masks were recommended, and age at least 60 years continued to be significant predictors of per-capita mortality (all  $P \le 0.001$ , Supplemental Table A5). The model explained 52.3% of the variation in per-capita mortality. Each week the infection persisted in a country without masks was associated with a 62.5% increase in per-capita

Table 2

Predictors of (log) country-wide per-capita coronavirus mortality by May 9 by multivariable linear regression in 196 countries

	10 <sup>coefficient</sup>	Coefficient (SE)	95% CI	P-value
Duration in country (weeks)	1.6193	0.209 (0.036)	0.138 to 0.281	< 0.001
Time wearing masks (weeks)	0.7174	-0.144 (0.030)	-0.204 to -0.084	< 0.001
Time in internal lockdown (weeks)	0.9761	-0.0105 (0.050)	-0.109 to 0.088	0.83
Time since the start of international travel restrictions (weeks)	0.8634	-0.0638 (0.035)	-0.133 to 0.005	0.07
Population, age ≥ 60 years (%)	1.1180	0.0485 (0.010)	0.028 to 0.069	< 0.001
Urbanization (%)	1.0139	0.00599 (0.004)	-0.001 to 0.013	0.10
Obesity prevalence (%)	1.0339	0.0145 (0.009)	-0.003 to 0.032	0.10
Temperature, ambient (C)	0.9904	-0.0042 (0.009)	-0.022 to 0.013	0.64
Constant	_	-7.659 (0.396)	−8.44 to −6.88	< 0.001

The duration of outbreak in country was from estimated date of first infection until 23 days before May 9, 2020 (i.e., April 16). Mask and lockdown durations run from the stated event (mask recommendation or lockdown) or estimated date of first infection in the country (whichever was later) until 23 days before May 9, 2020 (i.e., April 16). Model r<sup>2</sup> = 0.508.

mortality (Supplemental Table A5). By contrast, in countries where masks were recommended, the per-capita mortality tended to increase each week by 19.6% (because [1.6253] [0.7357] = 1.196, Supplemental Table A5). In this model, the prevalence of obesity was associated with increased country-wide per-capita mortality, although the association was not significant (P = 0.09). If the prevalence of obesity increased by 10% (e.g., from 10% to 20% of a population), the per-capita mortality tended to increase by 48% (Supplemental Table A5)

In this model, a 10-fold increase (i.e., one logarithm) in percapita testing tended to be associated with a 25.1% increase in reported per-capita mortality, although the positive association was not statistically significant (P = 0.40, Supplemental Table A5).

If early testing lowers mortality, one might expect negative regression coefficients. Testing on April 16 and on May 9 was added to the multivariable model of Table 3, using data from the 158 countries with both obesity and testing data by these dates. Per-capita testing (log) by April 16 was not negatively associated with per-capita mortality (log) by May 9 (coefficient 0.264, 95% CI: -0.323 to 0.851, P = 0.38).

Likewise, testing on April 4 (the earliest archived data) and on May 9 was added to the multivariable model of Table 3, using data from the 131 countries with both obesity and testing data by these dates. Per-capita testing (log) by April 4 was not significantly associated with per-capita mortality (log) by May 9 (coefficient -0.0504, 95% CI: -0.378 to 0.278, P=0.76). Given the coefficient, a 10-fold (one log) increase in early testing would be associated with a (nonsignificant) decrease in per-capita mortality of 11.0%.

Only five countries had performed over one test for every 10 people in the country by May 9, 2020: the Faeroe Islands, Iceland, the Falkland Islands, the UAE, and Bahrain. The highest mortality among this group was 29.0 per million population, seen in Iceland.

#### CONTAINMENT AND TESTING POLICIES

For 169 countries, containment, testing, and health policies were scored by Oxford University. The following countries with mask policies by April 16 were included in this analysis, but not in the previous multivariable model, for lack of data on numbers of tests performed: China, Macau, Cameroon, Sierra Leone, and Sudan. In univariate analysis, scores for school closing, canceling public events, international travel controls, and index of containment and health were significantly

associated with lower per-capita mortality (all P < 0.05, Table 3). Policies regarding workplace closing, restrictions on gatherings, closing public transport, stay-at-home requirements, internal movement restrictions, public information campaigns, testing, and contact tracing were not significant predictors of mortality (all P > 0.05, Table 3). Likewise, overall indices of stringency and government response were not associated with mortality (both P > 0.05, Table 3).

A multivariable model in 169 countries found that duration of the infection, duration masks were recommended, prevalence of age at least 60 years, obesity, and international travel restrictions were independently predictive of per-capita mortality (Table 4). The model explained 66.6% of the variation in per-capita mortality. At baseline, each week of the infection in a country without masks was associated with an increase in per-capita mortality of 50.7% (Table 4). By contrast, for each week that masks were worn, the per-capita mortality was associated with a lesser increase of 12.6% each week (given that 1.5072 [0.7471] = 1.126, Table 4).

International travel restrictions were scored by Oxford as (0) no measures, (1) screening, (2) quarantine arrivals from highrisk regions, and ban on arrivals from some (3) or all (4) regions. The international travel restrictions were scored as four in Greenland, 3.8 in Bermuda, 3.6 in Israel, 3.5 in Czechia and New Zealand, 3.1 in Taiwan, and 2.9 in Australia, and at the other extreme, were scored as 1.1 in Sweden, and as 0 in Iran, Luxembourg, and the United Kingdom.

International travel restrictions were associated with lower mortality, regardless of whether incorporated in the model as time since onset, or as mean score during the outbreak. We present the model based on the former because of the strength of the association, and for consistency with the models presented previously. The regression analysis suggested that for each week of travel restrictions (without masks), the per-capita mortality increased by 24.8% (given that 1.5072 [0.8283] = 1.248, Table 4).

Per-capita mortality was not significantly associated with policies regarding either testing policy (P = 0.91), or contact tracing (P = 0.06, Table 4). Testing policy was scored as no policy (0), symptomatic with exposure, travel history, hospitalization, or key occupation (1), all symptomatic (2), or open to anyone (3). Testing policy tended to be positively associated with mortality. Contact tracing was scored as none (0), some cases (1), or all cases (2), and tended to be inversely related with per-capita mortality (although not significantly). As compared with a country with no contact tracing policy, comprehensive contact tracing might be associated with a

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 $\label{eq:Table 3} \text{Government policies in 169 countries with low and high per-capita coronavirus mortality by May 9, 2020}$ 

	Mear	n (SD)	_
	Low mortality	High mortalilty	P-value
School closing (0–3)	2.08 (0.65)	1.84 (0.49)	0.006
Workplace closing (0-3)	1.21 (0.74)	1.34 (0.47)	0.19
Cancel public events (0-2)	1.39 (0.45)	1.21 (0.34)	0.005
Restrictions on gatherings (0-4)	2.00 (0.84)	1.76 (0.87)	0.07
Close public transport (0-2)	0.64 (0.51)	0.58 (0.45)	0.41
Stay-at-home requirements (0-3)	0.84 (0.61)	0.89 (0.46)	0.52
Internal movement restrictions (0-2)	0.92 (0.52)	0.85 (0.38)	0.33
International travel controls (0-4)	2.88 (0.72)	2.43 (0.83)	< 0.001
Income support (0-2)	0.15 (0.24)	0.55 (0.41)	< 0.001
Public information campaigns (0-2)	1.70 (0.36)	1.62 (0.44)	0.19
Testing policy (0–3)	1.12 (0.57)	1.05 (0.48)	0.35
Contact tracing (0–2)	1.08 (0.66)	1.02 (0.60)	0.53
Stringency index (0-100)	53.4 (14.6)	49.4 (12.9)	0.06
Government response index (0-100)	45.9 (11.7)	44.8 (10.7)	0.53
Containment and health index (0-100)	52.0 (13.1)	48.2 (11.7)	0.047
Economic support index (0–100)	11.9 (13.7)	26.0 (16.6)	< 0.001

Government policies were scored by Oxford University. 9 Characterization as low or high mortality was defined by the median for all 200 countries.

55.5% reduction in reported per-capita mortality (given that  $10^{2\times[-0.176]}=0.445$ ). However, statistical significance for this association was not demonstrated. Thus, testing and tracing may be important factors, but seem unlikely to account for most of the 100-fold variation in per-capita mortality between low- and high-mortality countries early in the course of the pandemic.

**Survey-modified model.** Surveys of mask-wearing by the public during the exposure period were available for 42 countries (Supplemental Table A2). To determine the influence that actual mask wear, as opposed to mask policies, might have on the model, we scored countries as mask-wearing if at least 50% of the public wore a mask, and non-mask-wearing if less than 50% of the population did so.

Based on surveys, Canada, Finland, France, Germany, and Malawi were not considered mask-wearing countries at any time during the exposure period (ending April 16). By contrast, Italy was scored as mask-wearing beginning March 19, Spain and India beginning March 21, Saudi Arabia beginning April 1, Russia beginning April 4, Singapore beginning April 10, and the United States, Brazil, and Mexico beginning April 12. 54,55

In this survey-modified model in 200 countries, duration of the outbreak, duration of mask wear, proportion of the population aged 60 years or older, and urbanization were all significant predictors of per-capita mortality (all P < 0.01,

Supplemental Table A6). Time since the start of international travel restrictions tended to be inversely associated with mortality (P = 0.051). Each week that the infection persisted in the country without masks was associated with a 59.9% increase in per-capita mortality. On the other hand, when masks were worn, the per-capita mortality only increased by 9.3% weekly (1.5993) (0.6836) = 1.093 (Supplemental Table A6). The model explained 48.3% of the variance in mortality.

#### DISCUSSION

These results confirm that in the first 4 months of 2020, there was marked variation between countries in mortality related to COVID-19. Countries in the lower half of mortality experienced an average COVID-19–related per-capita mortality of 0.99 deaths per million population, in contrast with an average of 93.3 deaths per million in the remaining countries. Depending on the model and dataset evaluated, statistically significant independent predictors of per-capita mortality included urbanization, fraction of the population aged 60 years or older, prevalence of obesity, and duration of the outbreak in the country. In addition, per-capita mortality was inversely (and independently) associated with international travel restrictions and the period of the outbreak subject to cultural norms or government policies favoring mask-wearing by the public.

TABLE 4

Predictors of (log) country-wide per-capita coronavirus mortality by May 9 by multivariable linear regression in 169 countries

7.51			
10 <sup>coefficient</sup>	Coefficient (SE)	95% CI	P-value
1.5072	0.1782 (0.031)	0.117 to 0.239	< 0.001
0.7471	-0.1266 (0.026)	-0.177 to -0.076	< 0.001
1.0184	0.0079 (0.043)	-0.077 to 0.093	0.85
0.8283	-0.0818 (0.030)	-0.140 to -0.023	0.006
1.1725	0.0691 (0.009)	0.051 to 0.087	< 0.001
1.0151	0.0065 (0.003)	-0.0003 to 0.013	0.06
1.0461	0.0196 (0.008)	0.003 to 0.036	0.02
1.0193	0.0083 (0.008)	-0.007 to 0.023	0.28
1.0298	0.0127 (0.111)	-0.207 to 0.233	0.91
0.6674	-0.176 (0.092)	-0.357 to 0.006	0.06
_	-7.885 (0.347)	−8.57 to −7.20	< 0.001
	1.5072 0.7471 1.0184 0.8283 1.1725 1.0151 1.0461 1.0193 1.0298 0.6674	1.5072	1.5072

The duration of outbreak in country was from estimated date of first infection until 23 days before May 9, 2020 (i.e., April 16). Mask and lockdown durations run from the stated event (mask recommendation or lockdown) or estimated date of first infection in the country (whichever was later) until 23 days before May 9, 2020 (i.e., April 16). Policies on testing, contact tracing, and international travel controls were scored by Oxford University. Model  $r^2 = 0.666$ .

These results support the universal wearing of masks by the public to suppress the spread of the coronavirus. Given the low levels of coronavirus mortality seen in the Asian countries which adopted widespread public mask usage early in the outbreak, it seems highly unlikely that masks are harmful.

The variation in national mask norms and recommendations at the start of the pandemic provided a unique opportunity to learn about the benefits of public mask wear. On April 30, 2020, we originally published the finding that the logarithm of per-capita coronavirus mortality is linearly and positively associated with the duration of the outbreak without mask norms or mandates. This key finding was recently confirmed using mortality data from June 24, 2020 by Goldman Sachs chief economist Hatzius. Their analysis confirmed that, for prediction of both infection prevalence and mortality, the significance of the duration of mask mandates or norms in the model persists after controlling for age of the population, obesity, population density, and testing policy. Other work has confirmed that wearing masks during the pandemic can provide substantial economic value.

Although a complete analysis of the later period in the pandemic is beyond the scope of the current model, we might note the coronavirus-related mortality among early-masking countries, on August 9, 2020. Among the 24 countries which initiated public mask-wearing within 20 days of the onset of their outbreak (Supplemental Table A1), the average coronavirus-related mortality was 4.7 per million (SD 6.1) on August 9. Moreover, among the additional 17 countries which recommended masks within 30 days of the start of their outbreak (Supplemental Table A1), the average coronavirus-related mortality was 26.6 per million (SD 36.2) on August 9. By contrast, the per-capita coronavirus mortality in the United States was 502 per million on August 9.

Currently, almost all countries now recommend masks in crowded, indoor spaces (Supplemental Table A2). Therefore, countries are distinguished primarily not by the stated recommendation, but by their actual mask-wearing. Surveys and observational data of mask-wearing by the public are unavailable for most countries. Our review of the literature is one of the more complete evaluations of the question to date. Available scholarship and surveys do corroborate reports in the news media that mask-wearing was common in public in many Asian countries, including Japan, the Philippines, Hong Kong, Vietnam, Malaysia, Taiwan, Thailand, China, Indonesia, India, Myanmar, and Bangladesh (Supplemental Table A2). Internet search data are consistent with interest in masks developing much earlier in the course of the pandemic in Asia than elsewhere. 75,76 Mask-wearing was widespread in some low-mortality countries even before, or in the absence of, a formal government recommendation.

Public mask-wearing is best assessed by direct observation, rather than by surveys. A low fraction of respondents reporting mask wear in a given week might still represent high compliance if few of them visited a crowded indoor space. Conversely, a high fraction reporting mask wear in a given week might represent poor compliance if the respondents only wore a mask during a portion of their outings, wore the mask incorrectly, or were less than forthright with their responses. Available observations do confirm high levels of mask wear in East Asia, with heterogeneity in some western regions.

In addition, it is likely that the policies favoring maskwearing in parts of the Middle East, Africa, Latin America, and the Caribbean were markers of a general cultural acceptance of masks that helped to limit the spread of the virus. Had there been adequate survey data to fully reflect the early wearing of masks in these regions, it is possible that the association of masks with lower mortality would be even stronger.

Conversely, in Western countries which had no tradition of mask-wearing, and which only recommended (rather than mandated) mask-wearing by the public, such as the United States, the practice has been steadily increasing, but change has not been immediate.

Much of the randomized controlled data on the effect of mask-wearing on the spread of respiratory viruses relate to influenza. One recent meta-analysis of 10 trials in families, students, or religious pilgrims found that the relative risk for influenza with the use of face masks was 0.78, a 22% reduction, although the findings were not statistically significant.<sup>77</sup> Combining all the trials, there were 29 cases in groups assigned to wear masks, compared with 51 cases in control groups.<sup>77</sup> The direct applicability of these results to maskwearing at the population level is uncertain. For instance, there was some heterogeneity in methods of the component trials, with one trial assigning mask-wearing to the person with a respiratory illness, another to his close contacts, and the remainder to both the ill and their contacts. 77 Mask-wearing was inconsistent. The groups living together could not wear a mask when bathing, sleeping, eating, or brushing teeth. 78-80 In one of the studies reviewed, parents wore a mask during the day, but not at night when sleeping next to their sick child.80 In a different trial, students were asked to wear a mask in their residence hall for at least 6 hours daily (rather than all the time).<sup>78</sup> The bottom line is that it is nearly impossible for people to constantly maintain mask wear around the people with whom they live. By contrast, wearing a mask when on public transit or shopping is quite feasible. In addition, as an infection propagates through multiple generations in the population, the benefits multiply exponentially. Even if one accepts that masks would only reduce transmissions by 22%, then after 10 cycles of the infection, mask-wearing would reduce the level of infection in the population by 91.7%, as compared with a non-mask-wearing population, at least during the period of exponential growth (because  $0.78^{10} = 0.083$ ). It is highly unlikely that entire countries or populations will ever be randomized to either wear, or not wear, masks. Public policies can only be formulated based on the best evidence available.

Some countries which used masks were better able to maintain or resume normal business and educational activities. For instance, in Taiwan, schools reopened on February 21, 2020, with parents directed to purchase four to five masks per week for each child.

Limits on international travel were significantly associated with lower per-capita mortality from coronavirus. On the other hand, nationwide policies to ban large gatherings and to close schools or businesses tended to be associated with lower mortality, although not in a statistically significant fashion. However, businesses, schools, and individuals made decisions to limit contact, independent of any government policies. The adoption of numerous public health policies at the same time can make it difficult to tease out the relative importance of each.

Our findings are consistent with observations that obesity is associated with negative outcomes, including intensive care 2408 LEFFLER AND OTHERS

unit admission and mechanical ventilation, in the setting of COVID-19. 81-83 Of course, some of the observed association of obesity with mortality may be the result of unknown confounders.

Colder average monthly temperature was not associated with higher levels of COVID-19 mortality when accounting for other independent variables. One reason that outdoor temperature might have limited association with the spread of the virus is that most viral transmission occurs indoors.84 We acknowledge that using the average temperature in the country's largest city during the outbreak does not model the outbreak as precisely as modeling mortality and temperature separately in each of the thousands of cities around the world. However, to a first approximation, our method did serve to control for whether the country's climate was tropical, temperate, or polar, and whether the outbreak began in late Winter (Northern Hemisphere) or late summer (Southern Hemisphere). Environmental factors which could influence either human behavior or the stability and spread of virus particles are worthy of further study.

Presumably, high levels of testing might identify essentially all coronavirus-related deaths, and still higher levels of testing, combined with contact tracing, might lower mortality. Statistical support for the benefit of mass testing could not be demonstrated. It seems likely that countries which test at a low level are missing many cases. We identified just five countries (Iceland, the Faeroe Islands, the UAE, the Falkland Islands, and Bahrain) which had tested more than one-tenth of their population by May 9. All five countries had a mortality of 29 per million (one in 34,480 people) or less. The degree to which these results would apply to larger, less isolated, or less wealthy countries is unknown. Statistical support for benefit of high levels of testing might be demonstrated if additional and more diverse countries are able to test at this level. The benefits of contact-tracing policies with respect to mortality were of marginal statistical significance (P = 0.06).

The model identified predictors of coronavirus-related mortality early in the course of the pandemic. It is conceivable that additional predictors of mortality might emerge with time. For instance, policies regarding internal lockdown and contact tracing might be associated with mortality as the pandemic progresses if these policies require a longer period to reach their full effect. Conversely, international travel restrictions might become less important over time, because if the virus becomes widespread within a country then closing the border will have a lesser impact.

One limitation of our study is that the ultimate source of mortality data is often from governments which may not have the resources to provide a full accounting of their public health crises, or an interest in doing so. Countries may vary in the accuracy of their reporting. It should be noted that the benefit of wearing masks persisted in a model which excluded data from China (Supplemental Table A5).

We acknowledge that country-wide analyses are subject to the ecologic fallacy. There is potential for confounding at the ecologic level, and information bias at both the individual and ecologic levels.

However, multiple studies of coronavirus morbidity and mortality have treated countries as the unit of analysis. 85-87 Assessment at the population level is particularly suitable for assessment of the effect of masks. If masks offer source control

by blocking the spread of respiratory droplets, then those who wear masks are protecting those who do not wear masks.

We modeled the growth of the pandemic as an exponential curve (which is linear with time on a logarithmic scale) because infectious diseases are often modeled as obeying exponential processes early in their course. We recognize that all mathematical models are merely idealizations of more complicated dynamics. Future modeling work could explore the utility of nonlinear terms (e.g., quadratic and cubic), particularly as the pandemic progresses.

Available surveys suggest that there can be a delay between recommendations and changes in actual mask wear. Similarly, there might be lag periods between changes in other policies or risks and corresponding changes in infection levels which were not accounted for by the model.

The source for mortality and testing data we selected is publicly available, has been repeatedly archived, to contains links to the source government reports for each country, agrees with other coronavirus aggregator sites,89 and has been used in other scholarly works. 85,90-96 We presented the per-capita mortality data in Supplemental Table A2. One might question whether any of these data sites or governments provide a complete and accurate picture of coronavirus mortality. But we must remember that this information does not exist in a vacuum. Independent sources confirm when mortality has been high. Social media alerted the world to the outbreaks in Wuhan, Iran, Italy, and New York. News reports have used aerial photography to confirm the digging of graves in Iran, New York, and Brazil. Long lines were seen to retrieve remains at crematoria in Wuhan. Mortuary facilities were inadequate to meet the demand in New York, and Guayaquil. Conversely, signs of health system overload have been noted to be absent in the countries reporting low mortality. The health systems in Hong Kong, Taiwan, Japan, and South Korea are believed to be transparent. Reporters in Vietnam have called hospitals and funeral homes to confirm the absence of unusual levels of activity. Therefore, although no source is perfect, we believe that the data we used are consistent with observations from nongovernmental sources, and comparable in reliability to that in other scholarly works.

It is not the case that countries which reported no deaths due to coronavirus simply were not exposed to the virus. All 200 countries analyzed did report COVID-19 cases. Several countries which traditionally use masks and sustained low mortality (or none) are close to and have strong travel links to China. Some of these countries reported cases early in the global pandemic (Supplemental Table A1). Community transmission has been described in Vietnam.

In summary, older age of the population, urbanization, obesity, and longer duration of the outbreak in a country were independently associated with higher country-wide percapita coronavirus mortality. International travel restrictions were associated with lower per-capita mortality. However, other containment measures, testing and tracing polices, and the amount of viral testing were not statistically significant predictors of country-wide coronavirus mortality, after controlling for other variables. By contrast, societal norms and government policies supporting mask-wearing by the public were independently associated with lower per-capita mortality from COVID-19. The use of masks in public is an important and readily modifiable public health measure.

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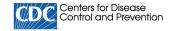
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## **ACT NOW!**









## COVID-19

## People at Increased Risk

And Other People Who Need to Take Extra Precautions

Updated Jan. 4, 2021

Print



## People at Increased Risk for Severe Illness

Some people are more likely than others to become severely ill

Older Adults

People with Medical Conditions

## Other People Who Need Extra Precautions

Factors that mean you might need to take extra precautions against COVID-19

Your Individual Situation

Racial and Ethnic Minority Groups

Pregnancy and Breastfeeding

People with Disabilities

Developmental and Behavioral Disorders

Drug Use and Substance Use Disorder

Where You Live

People Living in Rural Communities

People Experiencing Homelessness

Persons in Correctional and Detention Facilities

**Newly Resettled Refugee Populations** 

Nursing Home and Longer-Term Care Facilities

Group Homes for People with Disabilities



Resources for Limited-English-Proficient Populations

A communication toolkit with non-English COVID-19 resources

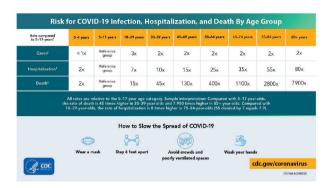
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Caring for People with Disabilities

Caring for People with Developmental and Behavioral Disorders

Caregivers of People Living with Dementia



Risk for COVID-19 Infection, Hospitalization, and Death By Race/Ethnicity

| Rate ration | Rate rati

Risk for COVID-19 Infection, Hospitalization, and Death by Age Group

Risk for COVID-19 Infection, Hospitalization, and Death by Race/Ethnicity

## **Digital Resources**



COVID-19: Are You at Higher Risk for Severe Illness?



ASL Video Series: COVID-19: Are You at Higher Risk for Severe Illness?





## Protect Your Health This Flu Season

Getting a flu vaccine during 2020-2021 is more important than ever because of the ongoing COVID-19 pandemic. Flu vaccination is especially important for people who are at high risk from flu; many of whom are also at high risk for COVID-19 or serious outcomes.

People at High Risk For Flu Complications

## More Information

**Prevent Getting Sick** 

How to Protect Yourself and Others

Symptoms and Testing

# List of Coronavirus-Related Restrictions in Every State

Some states have begun rolling back reopenings



Alexi Rosenfeld/Getty Images

En español | Governors across the country are issuing orders and recommendations to their residents on the status of schools, businesses and public services as their states respond to the coronavirus outbreak.

All states have taken coronavirus-related actions, but restrictions vary, and so does the length of time the measures are in place. Here's a look at each state's restrictions:

• Alabama: At the direction of Gov. Kay Ivey (R), the state health officer has extended a safer-at-home order until 5 p.m. on March 5. People over age 6 must wear masks in indoor public spaces, when using a transportation service or when outdoors in gatherings of 10 or more. Nonwork get-togethers are allowed, but individuals from different households must maintain a 6-foot distance from one another. Restaurants, bars and breweries can offer dine-in service, but party size is capped at eight people. Tables or booths must be placed 6 feet apart or, if within 6

feet, must be separated by partitions. Hair salons and similar personal-care businesses must also keep clients 6 feet apart or separate clients by partitions if within 6 feet. Retail stores and gyms are among the businesses that must implement sanitation and social distancing practices. Beaches are open, but patrons must practice social distancing. As of Oct. 2, hospital, nursing and long-term care facilities have been allowed to permit residents to receive one visitor at a time, subject to other restrictions.

- Alaska: Gov. Mike Dunleavy (R) modified a travel mandate on Feb. 14. Travelers arriving in Alaska must opt for one of several options, such as show a negative COVID-19 test or submit to a test on arrival. Critical infrastructure workers are exempt. Previously, Dunleavy permitted all businesses, including restaurants, hair salons, gyms, museums and entertainment venues, to reopen at 100 percent capacity. Safeguards are recommended. In group gatherings, individuals from separate households are encouraged to maintain a 6-foot distance from one another. Local authorities and private businesses may enact stricter requirements.
- Arizona: Gov. Doug Ducey (R) signed an order allowing restaurants to extend their premises for outdoor dining services. Restaurants can offer indoor dining service but must limit occupancy and must separate parties by at least 6 feet. Ducey also modified the rules for large gatherings. Organized events with more than 50 people are prohibited, but local authorities can approve them if certain safety precautions are met. Once approved, the local jurisdiction must post the mitigation efforts on its website and submit its plan to the state health department. Previously, Ducey and the Arizona Department of Health Services released requirements and guidelines for bars, gyms, movie theaters and water parks to reopen. Under the new guidance, the businesses can operate at a limited capacity if certain benchmarks are met. Travelers are free to visit the state without quarantining or providing proof of a negative COVID-19 test.

On Dec. 30, Ducey extended an order on driver's license renewals. A standard driver's license in Arizona expires when individuals turn 65, and renewal requires an in-office visit. Ducey's extension will allow seniors with a license that expires between March 1, 2020, and Feb. 28, 2021, to defer renewal for one year from the expiration date.

• Arkansas: Gov. Asa Hutchinson (R) signed an executive order that extended a mask mandate through March 31. Everyone age 10 or older must wear a mask, whether indoors or outdoors, if they are with non-household members and social

distancing cannot be maintained. (Face coverings aren't required at private residences.) The new order also converted health department directives pertaining to restrictions on businesses and gatherings to guidance. Restaurants, bars, gyms and large venues are no longer under capacity restrictions.

• California: Under the direction of Gov. Gavin Newsom (D), the health department has lifted a regional stay-at-home order that would go into effect if a region's intensive care unit availability fell below 15 percent. All regions are now under the state's Blueprint for a Safer Economy, with each county falling into one of four color-coded tiers: purple (where the coronavirus is most widespread), red, orange and yellow (where it is least prevalent).

Previously, Newsom permitted gatherings statewide, but no more than three households could attend, and the space had to be big enough to allow people to practice social distancing. In purple-tier areas, just outdoor gatherings are allowed. Restaurants can offer only outdoor dining, and retail stores must limit capacity to 25 percent. Hair salons and barbershops can offer indoor service, with restrictions. Gyms and fitness centers can open for outdoor activities. Many other nonessential businesses — such as nightclubs, theme parks and concert venues — remain closed.

In red-tier counties, restaurants can resume indoor dining at 25 percent capacity or 100 patrons, whichever is fewer. Retail stores may operate at 50 percent capacity, and museums can reopen indoors at 25 percent capacity. For counties in the orange tier, bars and breweries that don't serve food are among businesses that can reopen for outdoor service. For counties in the yellow tier, most businesses can reopen but must follow safety precautions.

For a full list of restrictions, visit covid19.ca.gov. The governor has ordered everyone to wear a face mask in public spaces; children under age 2 and people with certain medical disabilities are among those exempt. He also signed a bill into law that requires businesses to report COVID-19 outbreaks to local officials as well as to employees who may have been exposed to the coronavirus while at work.

• Colorado: Under the direction of Gov. Jared Polis (D), the health department updated the state's Dial framework to Dial 2.0, a tool that determines restrictions by county. Counties fall into one of six color-coded levels of risk, depending on the incidents of COVID-19. Level green is the least restrictive, under which businesses can operate at 50 percent capacity or 500 people, whichever is smaller. In level-blue counties, public and private gatherings cannot exceed 10 participants

or people from more than two households. Restaurants, indoor event venues and houses of worship can operate at 50 percent capacity or 175 people, whichever is smaller. In yellow counties, public and private gatherings cannot exceed 10 participants or people from more than two households. Restaurants and indoor event venues can operate at 50 percent capacity, with a maximum of 50 people per room (the maximum might be higher for larger establishments). In orange counties, public and private gatherings cannot exceed 10 participants or people from more than two households. Restaurants can operate at 25 percent capacity, with a maximum of 50 patrons per room. In red counties, restaurants must halt indoor dining, but outdoor table service, delivery and takeout are permitted. Gatherings with members outside the household are prohibited, and indoor events are closed. Limited exceptions include gatherings at houses of worship, which can operate indoors at 25 percent capacity or 50 people (whichever is smaller). Outdoor events are limited to 25 percent capacity or 75 people (whichever is smaller). Retail stores can operate at 50 percent capacity and personal care services at 25 percent capacity. Gyms can operate at 10 percent capacity, with a maximum of 10 people. No counties are in the most restrictive purple level. The amended order took effect Feb. 6.

A mask mandate remains in effect. People 11 and older must wear a face covering in indoor public spaces or while using public transportation or ride-hailing services. Workplaces can deny service or admission to customers who aren't wearing a face mask. An organization can request a waiver from the state for certain indoor activities if wearing a mask during an activity is not practical.

• Connecticut: Gov. Ned Lamont (D) extended a curfew on some businesses by one hour. Restaurants must now close by 11 p.m. (instead of 10 p.m.). They must continue to restrict indoor dining to 50 percent capacity, among other restrictions. Events at commercial and entertainment venues, such as movie theaters and bowling alleys, must also close by 11 p.m. Last November, the state rolled back its reopening plan from phase 3 to phase 2.1. At private residences, indoor and outdoor gatherings are capped at 10 people. At commercial establishments, indoor events are capped at 25 people and outdoor gatherings are capped at 50. Indoor worship services are limited to 50 percent of the venue's capacity. Personal-service businesses and libraries can remain at 75 percent capacity, among other phase 3 rules.

Lamont authorized local health directors to impose a \$10,000 fine per violation on businesses that hold events over capacity limits. Previously, he ordered anyone over age 2 to wear a face covering in public places, indoors or outdoors, when

- social distancing cannot be maintained. Masks must be worn at gyms and fitness centers even with social distancing. In December, the governor amended a travel mandate. Visitors arriving from out of the state or country must fill out a health form and self-quarantine for 10 days. To avoid self-quarantine, travelers can show proof of a negative coronavirus test taken 72 hours prior to arrival. Essential workers are exempt, as are travelers arriving from New York, New Jersey or Rhode Island.
- **Delaware:** Gov. John Carney (D) modified coronavirus-related restrictions on gathering limits for phase 2 reopenings. Effective Feb. 19, public indoor gatherings are limited to 50 percent of the venue's fire occupancy or 25 people, whichever is smaller. With permission from the health department, public indoor gatherings of up to 150 people are allowed. Outdoor public gatherings are capped at 50 people, but groups of up to 250 can gather with permission from the health department. Get-togethers at private residences cannot exceed 10 people. Previously, Carney lifted an advisory that encouraged individuals to stay at home except for work or other essential activities. He also increased capacity for some businesses. Restaurants can increase indoor dining to 50 percent of the venue's fire occupancy, but only customers from the same household can sit together. Retail stores, gyms and most other businesses can also operate at 50 percent capacity, among other restrictions. Individuals must wear a face covering when in indoor public places, including grocery stores and on mass transit, and when in outdoor public spaces where social distancing cannot be maintained.
- District of Columbia: Mayor Muriel Bowser's (D) suspension of some Phase 2 activities expired Jan. 22. Indoor dining can resume at 25 percent capacity or 250 people (whichever is smaller). Museums and libraries can also reopen at 25 percent capacity, although the Smithsonian museums haven't reopened. Grocery stores and big-box retailers can continue to operate, but they must implement social distancing and limit occupancy. Indoor gatherings are capped at 10 people; outside gatherings are limited to 25. Visitors to Washington coming from areas with a high rate of infection must either get a coronavirus test 72 hours before arrival and be tested again three to five days after arrival or self-quarantine for 14 days. District residents returning from other states must limit their activities for two weeks or get tested upon their return; residents of Maryland and Virginia are exempt. The mayor ordered people older than 2 to wear a mask when leaving their residence if more than fleeting contact with others is likely. Masks also must be worn on National Park Service—managed lands, including trails, when physical distancing cannot be maintained.

Previously, Bowser prohibited high-contact team sports, such as basketball, football and soccer. High schools, recreation centers and sports clubs must suspend all physical sports and organized athletic activities for high schoolers. Middle schoolers and younger students can continue with drills or clinics for high-contact sports, as long as there is no physical contact among players and groups don't exceed 12 people.

- Florida: Gov. Ron DeSantis (R) signed an order lifting most coronavirus-related restrictions and moving the state to Phase 3 of its reopening plan, under which all businesses can reopen. Restaurants and bars are no longer subject to occupancy restrictions. However, city or county governments can impose occupancy limits on restaurants and bars (to as low as 50 percent capacity) if authorities state in the local order why the restriction is necessary for public health. DeSantis' new order also removes fees or penalties for individuals who don't follow social distancing practices, including mask mandates. The order went into effect Sept. 25.
- Georgia: Gov. Brian Kemp (R) signed an order extending restrictions related to COVID-19 through March 15. People living in long-term care facilities and other at-risk individuals, such as those with severe lung or heart disease, must continue to shelter in place. Kemp has strongly encouraged all residents to wear a face mask while outside their home but stopped short of requiring it. Gatherings of up to 50 people are allowed, but participants must maintain a 6-foot distance from one another. Restaurants must adhere to strict sanitation and social distancing guidelines. Gyms, hair salons and movie theaters are among businesses that can operate, with restrictions.
- Hawaii: Gov. David Ige (D) mandated that people arriving in Hawaii from out of state must show a negative COVID-19 test result obtained within 72 hours pretravel or self-quarantine for 10 days. Some islands require a second test, post-arrival. As of Dec. 2, travelers arriving in Kauai must quarantine for 14 days with or without a negative test. A statewide mask mandate requires individuals age 5 and over to wear a face mask in public spaces. Most of the state is under the Act With Care plan for reopening, which allows many businesses to resume operations, with restrictions. Each county has its own restrictions on gatherings.
- Idaho: Gov. Brad Little (R) signed an order that moves the state to Stage 3 of its reopening plan. Indoor or outdoor gatherings of up to 50 people are allowed. Religious and political gatherings are exempt from size restrictions, but social distancing and sanitation measures must be in place. With permission, events such as weddings and funerals may also exceed participant limits. The organizer must

apply for an exemption with the local health department. Restaurants, bars and nightclubs can continue to operate. Tables must be spaced 6 feet apart, and customers must remain seated unless arriving, leaving or using the restroom. Little has not issued a statewide mask mandate, but individuals over age 5 must wear a mask at long-term care facilities. Businesses may remain open but must take steps to limit close interactions when serving patrons, among other restrictions.

• Illinois: After placing all of the state in Tier 3 mitigation measures last November, Gov. J.B. Pritzker (D) announced that regions that have met certain benchmarks can move to looser Tier 2 or Tier 1 restrictions. For regions remaining in Tier 3, businesses should have employees work remotely as much as possible. Restaurants and bars must close between 11 p.m. and 6 a.m. and cannot offer indoor service. Outdoor dining is permitted, but reservations are required, tables must be spaced 6 feet apart and party size is limited to six people. Movie theaters, bowling alleys and other indoor recreational venues must close. Grocery stores must limit capacity to 50 percent, and retail stores may not surpass 25 percent capacity. Gyms and fitness centers must also limit capacity to 25 percent and cannot hold indoor classes. Personal-care services must limit capacity to 25 percent, with a maximum of 25 people. People are encouraged to gather only with those in their household.

Under Tier 2, restaurants and bars must follow the same rules as Tier 3. People are encouraged to limit gatherings to 10 people. Cultural institutions can reopen with restrictions, and indoor fitness classes of up to 10 people are allowed. Under Tier 1, restaurants and bars may offer indoor service at 25 percent capacity or 25 guests, whichever is smaller. Party size is limited to four, with a two-hour time limit. The 11 p.m. curfew still applies. Most businesses in Tier 1 fall under the Phase 4 rules of the original Restore Illinois plan, established last year.

A statewide mask mandate requires anyone over age 2 to wear a face covering when indoors in a public space or when outside if a 6-foot distance between people cannot be maintained.

• Indiana: Gov. Eric Holcomb (R) announced that he is extending, through March 31, an order that implements a county-by-county approach to restrictions. Effective March 1, counties designated as red or orange (areas with the highest risk of coronavirus spread) must limit social gatherings to 25 percent of a facility's capacity. Counties designated as yellow must limit gatherings to 50 percent of a facility's capacity. Counties designated as blue can operate at full

capacity, as long as social distancing, mask wearing and other precautions are followed. A statewide mask mandate remains in effect. People must wear a face covering when in an indoor public space, when outside if social distancing cannot be maintained and when using public transportation. As of Jan. 3, hospitals no longer had to suspend in-patient elective medical procedures, but they should postpone them if doing so is necessary to provide sufficient capacity for COVID-19 patients. Previously, Holcomb lifted nearly all restrictions on businesses.

Indianapolis Mayor Joe Hogsett (D) announced that, effective March 1, in Marion County, indoor bars and gyms can increase capacity to 50 percent and restaurants can increase capacity of indoor dining to 75 percent.

- **Iowa:** Gov. Kim Reynolds (R) signed a proclamation lifting a mask mandate and other coronavirus-related restrictions, effective Feb. 7. Individuals age 65 and older are encouraged, but not required, to limit activities outside of the home. Businesses, including restaurants, bars, movie theaters and hair salons, are strongly encouraged to take precautionary measures to reduce the transmission of COVID-19. Mass gatherings and events have no limits on size, but people are encouraged to practice social distancing.
- Kansas: Gov. Laura Kelly (D) issued a mask mandate, effective Nov. 25. Individuals over age 5 must wear a face covering in indoor public spaces, when obtaining health care services, while using transportation services, or in outdoor public spaces if a 6-foot distance between non-household members cannot be maintained. Businesses must also require employees, customers and visitors to wear a face mask when in an enclosed space where social distancing cannot be maintained, or when in an area where food is being prepared or packaged, among other circumstances. Counties can opt out of the mandate or issue their own. Previously, Kelly announced that counties should come up with their own plans to reopen businesses. A statewide plan to restart the economy in phases offers guidance, but counties aren't required to follow it. The state Department of Health and Environment mandated a 14-day home quarantine for people arriving in Kansas who traveled to certain states or countries with widespread transmission or attended an out-of-state mass gathering and didn't wear a mask and practice social distancing. The mandate also applies to anyone who traveled on a cruise ship on or after March 15.
- **Kentucky:** Gov. Andy Beshear (D) extended a mask mandate for another 30 days, through March. The mandate requires anyone over age 5 to wear a face covering while inside a public space, while using public transportation or while

- outdoors if social distancing cannot be maintained. After forcing restaurants to close indoor dining in early December, Beshear signed an order permitting restaurants and bars to reopen for indoor dining at 50 percent capacity. Restaurants and bars must stop food and drink service by 11 p.m. and close by midnight. Delivery and pickup may continue after those hours. A restriction on private indoor gatherings has expired, but Beshear continues to recommend a cap of eight people and no more than a mix of two households. Indoor event venues, theaters and gyms must limit occupancy to 50 percent capacity. Retail stores and personal care services, such as hair salons, must also limit capacity to 50 percent.
- Louisiana: Gov. John Bel Edwards (D) announced he is extending a modified version of Phase 2 restrictions for at least three more weeks. The order was set to expire Feb. 10. Restaurants must reduce indoor dining capacity to 50 percent and must stop serving alcohol by 11 p.m., among other restrictions. Bars must suspend indoor food and drink consumption in parishes with a high rate of COVID-19. Outdoor service is permitted, but seating is capped at 50 patrons. In parishes with a low positivity rate, bars can reopen for indoor dining at a limited capacity, but alcohol service must stop at 11 p.m. Hair salons, beauty shops and gyms are among businesses that must reduce capacity to 50 percent (down from 75 percent) and close waiting areas, among other restrictions. Retail stores, too, must limit capacity to 50 percent. Amusement parks, concert halls and children's indoor play centers are among businesses that must remain closed. Indoor social gatherings are capped at 75 people or 25 percent capacity of the facility. Social events held outside are capped at 150 people or 25 percent capacity unless individuals from separate households can maintain a 6-foot distance from one another. People 8 and older must wear a mask in public spaces, indoors or outdoors, unless social distancing can be maintained.
- Maine: Gov. Janet Mills (D) ended the 9 p.m. curfew for restaurants, movie theaters, performing arts venues and other businesses. The state is in Phase 4 of its reopening plan. Indoor gatherings are limited to 50 people, including at restaurants, movie theaters and other businesses with inside seating. A 6-foot distance between seating areas is required, among other precautions. Bars and tasting rooms can offer outdoor dining only. Gyms and other indoor businesses without seating must cap occupancy at 50 people. Retail operations can allow five customers per 1,000 square feet. Outdoor gatherings remain limited to 100 people. Face coverings are mandatory statewide for anyone 5 and older in public spaces, even if social distancing can be maintained. A travel mandate requires those

visiting Maine to show a negative COVID-19 test or self-quarantine for 10 days. Travelers from some states, including Vermont and New Hampshire, are exempt.

• Maryland: Gov. Larry Hogan (R) amended and restated the state's reopening plans. Retail stores and religious centers must continue to restrict operations to 50 percent of the venue's maximum occupancy. Fitness centers and personal-service businesses, such as beauty salons and barbershops, can also continue to operate at 50 percent capacity, with restrictions. Senior centers remain closed. Restaurants must keep dine-in service to 50 percent capacity, but the new order lifted a restriction, effective Feb. 1, that closed on-premises dining between 10 p.m. and 6 a.m. Restaurants continue to be prohibited from offering buffets, among other measures. The new order also extends a mask mandate. People older than 5 must wear a face covering in the public spaces of all businesses or areas outdoors where social distancing cannot be maintained. Previously, under Hogan's direction, the health department has recommended a cap of 10 people at private indoor and outdoor gatherings.

In Montgomery County, the County Council voted to lift a ban on indoor dining. Effective at 7 a.m., Feb. 14, restaurants can resume indoor dining at 25 percent capacity. Meals must be limited to no more than 90 minutes.

• Massachusetts: Gov. Charlie Baker (R) announced he is further loosening some restrictions on businesses. Effective March 1, the state moved to Step 2 of Phase 3. Restaurants are no longer under capacity limits, but tables must be spaced 6 feet apart and parties are limited to six people. Restaurants must continue to impose a 90-minute limit on dining. Retail stores, offices, movie theaters, places of worship, gyms and museums are among businesses that can increase capacity to 50 percent (up from 40). Indoor performance venues, like concert halls, can also operate at 50 percent capacity but must cap attendance at 500 people. Private indoor gatherings remain capped at 10 people, and outdoor get-togethers are limited to 25 participants. Everyone over age 5 must wear a mask in public places, indoors and outdoors. Masks must also be worn in gyms and athletic facilities at all times.

Previously, Baker ordered travelers entering the state, including returning residents, to self-quarantine for 10 days or show a negative COVID-19 test result. Visitors from states with low rates of COVID-19 are among those who are exempt.

• Michigan: The health department lifted restrictions that shuttered indoor dining and adjusted gathering guidelines. Restaurants and other food establishments can

offer indoor service at 25 percent capacity. Parties cannot exceed six people, and eateries must close by 10 p.m. Outdoor dining, takeout and delivery are allowed. Indoor gatherings at private residences or nonresidential venues are limited to 10 participants and cannot include people from more than two households. Outdoor get-togethers at private residences are capped at 25 people, with members from no more than three households. Limits on outdoor gatherings at nonresidences vary depending on whether there is fixed seating but are restricted to 25 people. Movie theaters, bowling alleys, fitness centers and casinos can reopen with restrictions. Personal-care businesses, such as hair salons, can remain open but must follow contact tracing requirements. Nightclubs remain closed. A mask mandate remains in effect. Individuals 5 and older must wear a face mask at gatherings; exceptions include while eating or drinking or while exercising outside if a 6-foot distance from others can be consistently maintained. The order remains in effect until March 29.

On Oct. 2 the Michigan Supreme Court struck down orders from Gov. Gretchen Whitmer (D) outlining pandemic-related restrictions. The court ruled that a 1945 law that Whitmer relied on to issue the orders was unconstitutional, and that the governor thus lacked the authority for her actions. In response to the ruling, the state health department has issued the new orders by drawing on another law.

• Minnesota: Gov. Tim Walz (D) signed an order, effective Feb. 13, that loosened restrictions for businesses. Restaurants can offer indoor dining at 50 percent capacity, with a maximum of 250 people. Parties are limited to six people, and indining services must close by 11 p.m. Takeout and delivery are permitted. Gyms and fitness centers can operate at 25 percent capacity or 250 people, whichever is smaller. Group workout classes of up to 25 people are allowed, and masks must be worn in gyms and fitness centers at all times. Outdoor and indoor entertainment venues can operate at 25 percent capacity, with a maximum of 250 people. Masks are required at indoor entertainment venues and strongly recommended at outdoor entertainment venues. Personal care businesses, such as hair salons and tattoo parlors, can operate, but customers must make an appointment; capacity is limited to 50 percent and social distancing practices must be implemented.

Gathering restrictions at private residences and non-venue settings remain in place. Members from no more than two households can gather indoors, with a maximum of 10 people. Outdoors, members from no more than three households can gather, with a maximum of 15 people. Previously, Walz ordered that people over age 5 must wear a mask when inside a business or public space or when

using public transportation, a taxi or a ride-hailing service. Workers must wear a mask outdoors if social distancing cannot be maintained.

- Mississippi: Gov. Tate Reeves (R) extended a mandate until March 3 that requires people in counties with high infection rates to wear a face mask in public spaces. Individuals statewide must wear masks when inside a school. The order also extends restrictions on social gatherings. When social distancing cannot be maintained, indoor gatherings are limited to 10 people and those held outside are restricted to 50. Some gatherings are exempt, such as those of religious organizations or students meeting in classrooms. Bars and restaurants may serve alcohol to seated patrons only and not after 11 p.m. Customers must be screened for illness prior to entry, and party size cannot exceed 10. Movie theaters and auditoriums must limit ticket sales to 50 percent of seating capacity. Most other businesses must limit customers or visitors to 75 percent capacity and implement safety precautions. Health care facilities that perform nonelective procedures must reserve 10 percent of their capacity for COVID-19 patients.
- Missouri: Gov. Mike Parson (R) announced that the state will fully reopen on June 16. According to a press release issued by the governor's office, "All statewide restrictions will be lifted, though local officials will still have the authority to put further rules, regulations or ordinances in place." Parson encouraged people to maintain social distancing and take precautions, such as practicing good hygiene and avoiding large crowds.
- Montana: Gov. Greg Gianforte (R) issued a directive allowing a statewide mask mandate to expire. The directive stated that local jurisdictions may implement a mask mandate. Gianforte also issued a directive encouraging businesses to develop and implement appropriate social distancing, safety and sanitation practices. Previously, the governor lifted coronavirus-related restrictions put in place by his predecessor, Steve Bullock, such as gathering limits and curfews on businesses.
- Nebraska: Gov. Pete Ricketts (R) announced changes to the state's directed health measures. Effective Jan. 30, the state moved from the blue to the green phase of its reopening plan. Indoor gatherings at theaters, arenas, stadiums, auctions and similar establishments can increase to 100 percent capacity. Parties are encouraged, but not required, to maintain a 6-foot distance from one another. Those wishing to hold events of 500 people or more must submit a plan to the local health department. Restaurants, bars, gyms, fitness centers and salons are

among businesses that can operate at 100 percent capacity and without restrictions. Businesses are encouraged to follow recommended guidance.

## How Social Distancing Helps Everyone

• Nevada: Gov. Steve Sisolak (D) modified current restrictions, effective Feb. 15. Public gatherings are capped at 35 percent capacity or 100 people, whichever is smaller. Private gatherings at residences cannot exceed 10 people inside and 25 people outside (unless everyone is from the same household). Businesses such as restaurants, bars, gyms, amusement parks and casinos are among those that can increase operations to 35 percent of fire-code capacity. Restaurants and food establishments must limit parties to six people. Retail and grocery stores can continue to operate at 50 percent of fire-code capacity, with other safety and sanitation protocols in place. Houses of worship, libraries and museums are among places that can now operate at 50 percent capacity.

It's anticipated that by March 15, gathering sizes will increase again, and most businesses will be permitted to operate at 50 percent capacity. People over age 9 must wear a face covering whenever they leave home, indoors or outdoors, including at private gatherings or at an indoor gym, fitness center or dance studio.

- New Hampshire: Gov. Chris Sununu (R) extended a mask mandate through March 26. The order requires individuals over age 5 to wear face coverings in indoor or outdoor public spaces if social distancing with people from other households cannot be maintained. Exceptions include people who are exercising, in school or eating or drinking. Restaurants can offer both indoor and outdoor service, but tables should be spaced 6 feet apart, among other guidelines. Gyms can reopen at 50 percent capacity. Previously, Sununu permitted retail stores, hair salons, barbershops and similar businesses to reopen, with restrictions. Travelers, visitors and residents arriving in the state must meet self-quarantine restrictions. Exceptions include those arriving from another New England state who traveled for essential purposes. Individuals who have been vaccinated are also exempt, as long as 14 days have passed since the final dose.
- New Jersey: Gov. Phil Murphy (D) signed an order that loosens restrictions on capacity limits for religious gatherings. Religious services, weddings and funerals are among indoor gatherings that can allow up to 50 percent of the venue's capacity. The new order also allows large entertainment venues, such as stadiums, to allow people to attend events at 10 percent of the venue's capacity if indoors and 15 percent if outdoors. Previously, Murphy loosened restrictions on

restaurants, bars and other food establishments to allow them to operate at 35 percent capacity (up from 25 percent). Movie theaters, indoor performing arts centers and other entertainment facilities may operate at 35 percent capacity with a maximum of 150 people. Gyms, athletic facilities and personal care businesses, such as nail salons and barbershops, can also operate at 35 percent capacity. Murphy lifted restrictions for youth and adult indoor sports. Indoor practices and games for organized sports can now resume. Indoor interstate youth sports remain prohibited.

Indoor gatherings are capped at 10 people and outdoor gatherings cannot exceed 25 individuals. Murphy ordered people to wear face coverings when outside in public spaces if social distancing cannot be maintained. Wearing cloth masks is required in grocery stores and other indoor public spaces, including indoor gatherings.

- New Mexico: Under the direction of Gov. Michelle Lujan Grisham (D), the health department moved to a color-coded framework where a county's restrictions depend on virus risk. In high-risk red counties, indoor dining isn't permitted, outdoor dining is limited to 25 percent capacity and food establishments that serve alcohol must close by 9 p.m. Most businesses can operate at 25 percent capacity with maximum customer limits that depend on the type of establishment (for example, close-contact businesses are capped at 10 people). Gatherings are limited to 5 people. In yellow counties, gathering limits increase to 10 people. Restaurants can operate at 25 capacity indoors, 75 percent capacity outdoors and, if they serve alcohol, must close by 10 p.m. Customer limits at other businesses can increase. In green counties, gatherings of up to 20 people are allowed. Restaurants can operate at 50 percent capacity indoors and 75 percent capacity outdoors. Most other businesses can operate at 50 percent capacity. Essential businesses aren't subject to capacity restrictions. Individuals statewide must wear a mask when in a public space.
- New York: Gov. Andrew Cuomo (D) announced new guidelines for nursing home visitors. Effective Feb. 26, nursing homes that meet certain benchmarks can receive visitors. Depending on the benchmark, visitors may be required to present evidence of a negative COVID-19 test or take a rapid test on-site. Proof of vaccination is also acceptable. Previously, Cuomo signed an order extending the closing time for restaurants, bars and gyms, among other businesses, from 10 p.m. to 11 p.m., and he lifted a ban on indoor dining in New York City. The state is in Phase 4 of its reopening plan. Restaurants in New York City can resume indoor dining at 25 percent capacity. Regions outside of New York City can resume dine-

in service at 50 percent capacity. Zoos, nature parks, outdoor museums and other low-risk outdoor arts and entertainment venues can reopen at 33 percent capacity; indoor arts and entertainment venues can open at 25 percent capacity; and gyms and fitness centers can operate at 33 percent capacity. Movie theaters can reopen in some counties at 25 percent capacity, with no more than 50 people per theater. Since Nov. 13, indoor and outdoor private gatherings at residences have been limited to 10 people statewide.

Out-of-state travelers arriving in New York who want to opt out of a 10-day quarantine requirement must get tested no longer than three days before arriving, quarantine for three days upon arrival and get tested again on day four. Both tests must be negative to avoid a 10-day quarantine. Essential workers and travelers from bordering states are exempt. Individuals over age 2 must wear a face mask in public if social distancing cannot be maintained. The governor also issued an order permitting businesses to deny entry to anyone not wearing a mask. Cuomo extended a pause on evictions for those who cannot pay rent because of a COVID-19 hardship.

Previously, Cuomo lifted nearly all of the state's micro-cluster zone designations. The few areas that still fall within a micro-cluster zone must follow tighter restrictions.

• North Carolina: Gov. Roy Cooper (D) signed an order that lifted a curfew and eased restrictions, effective Feb. 25 at 5 p.m. Activities that involve exercising First Amendment rights, such as religious gatherings, are exempt. Most businesses, including gyms, museums, retail stores and hair salons, can operate at 50 percent capacity with other restrictions in place. Indoor bars and movie theaters can operate at 30 percent capacity or 250 people, whichever is smaller. Restaurants may offer indoor service at 50 percent capacity if tables are spaced 6 feet apart, among other restrictions. Sale of alcoholic beverages for on-site consumption must end by 11 p.m. Indoor get-togethers are capped at 25 people; those held outside are capped at 50. Very large indoor venues, such as stadiums, can admit up to 15 percent of occupancy limits.

The order also extends a mask mandate. Unless at home, individuals age 5 and older must wear a face covering in any indoor place when around people not from their household, whether or not social distancing can be maintained. People must also wear a mask outdoors unless they can consistently maintain a distance of 6 feet from those outside their household. Masks must be worn while exercising in

gyms or exercising outdoors within 6 feet of a non-household member. The new order lasts until March 26.

- North Dakota: Under the direction of Gov. Doug Burgum (R), the state health officer adjusted restrictions on certain businesses. Effective Jan. 29, the state moved from a moderate (yellow) risk level designation to a low (green) risk level classification. Restaurants and other food establishments can increase services to 80 percent capacity or 300 people, whichever is smaller. Event venues, such as ballrooms, are limited to 75 percent capacity with a cap on the number of people. The cap differs based on the designation for each county under the state's Smart Restart plan. A statewide mask mandate expired in January.
- Ohio: Gov. Mike DeWine (R) lifted a curfew that required individuals to stay in their homes between 11 p.m. and 5 a.m. but said it could be reinstated if hospitalization rates increase. Under the current health advisory to reopen the state's economy, gyms and other fitness venues may resume operations if they follow safety protocols. Restaurants can offer table service indoors, with restrictions. As of Feb. 12, restaurants could reopen self-service stations with sanitation and safety measures in place. Retail stores may reopen, but certain sanitation and social distancing practices must be implemented. Hair salons and other close-care businesses can reopen if they abide by strict sanitation rules. Nonessential medical procedures may resume, and nonessential offices and construction and manufacturing businesses may restart operations. Some sports competitions can resume, but strict restrictions, such as daily symptom assessments, must be in place. DeWine also advised travelers arriving in Ohio from states with a high rate of COVID-19 to self-quarantine for 14 days, but he stopped short of requiring it.

People statewide are required to wear face coverings when inside a location that is not a residence, when using public transportation or when outside if a 6-foot distance between non-household members cannot be maintained. Children younger than 10 and individuals with certain medical conditions are among those exempt. Stores are required to have signs about face coverings and to ensure that employees and customers wear masks. A retail compliance unit will conduct inspections to make sure stores are complying with the order. Gatherings of more than 10 people have been prohibited since April.

• Oklahoma: Under the direction of Gov. Kevin Stitt (R), the health department updated the county-by-county designation for COVID-19 risk. Guidance for individuals in counties in the moderate (orange) phase encourages small

gatherings, limiting travel and wearing a face mask in public spaces. Guidance for businesses includes offering teleworking options for employees when possible. Businesses should also implement sanitation and social distancing practices. One county has moved to the low (yellow) phase for COVID-19 risk. Businesses are encouraged to implement flexible work arrangements, and those holding large gatherings should take hygiene and safety measures. Previously, Stitt ordered that individuals wear masks in state buildings.

• Oregon: Gov. Kate Brown (D) announced modifications to coronavirus-related restrictions. Current restrictions depend on a county's risk level. In red counties, businesses must require remote work if possible. Indoor dining is prohibited. Outdoor dining is capped at 50 people and cannot include more than six individuals in a party. Retail stores can operate at 50 percent occupancy. Houses of worship may operate at 25 percent occupancy with a maximum of 100 people indoors or 150 people outdoors. Movie theaters, gyms and other indoor entertainment and recreational venues that are 500 square feet or larger can allow up to four groups with a cap of six individuals in each group. For facilities smaller than 500 square feet, one-on-one customer experiences are allowed (e.g., personal training). Private gatherings, indoors or outdoors, cannot exceed six people.

In orange counties, up to eight people are permitted for outdoor private gatherings. Restaurants can offer indoor dining at 25 percent capacity or 50 people, whichever is smaller. Indoor entertainment and fitness facilities can also operate at 25 percent capacity or 50 people. In yellow counties, restaurants can offer indoor dining at 50 percent capacity with a maximum of 100 people, and outdoor dining with up to 150 people. Indoor private gatherings cannot exceed eight people, and outdoor private gatherings are capped at 10.

In green counties, indoor private gatherings of up to 10 people are allowed, while outdoor private gatherings are limited to 12 people. Restaurants, gyms and entertainment venues are among businesses that can operate at 50 percent capacity. In red, orange and yellow counties, food and drink establishments must close by 11 p.m. In green counties, food and drink establishments must close by midnight.

Previously, Brown ordered people 5 and older to wear face coverings in outdoor areas where a 6-foot distance cannot be maintained and in indoor public spaces.

• **Pennsylvania:** Under the direction of Gov. Tom Wolf (D), the health department modified restrictions on gatherings. Effective March 1, gatherings are limited to 15 percent of a venue's capacity if indoors and 20 percent if outdoors. Participants

must wear masks and adhere to social distancing and other safety measures. Wolf signed an order that lifts restrictions on travelers. Effective March 1, visitors and returning residents are no longer required to show a negative COVID-19 test or self-quarantine. A mask mandate remains in effect. Restaurants, bars and other food establishments can resume indoor dining at limited capacity. Alcohol sales must stop after 11 p.m. daily. Gyms, fitness centers, movie theaters, museums and other indoor entertainment venues can also reopen at limited capacity. Individuals age 2 and older must wear a face covering in indoor public zones. Masks are also required outside if a 6-foot distance between nonhousehold members cannot be maintained. Previously, the governor announced that Pennsylvania Turnpike tollbooths will stop taking cash.

• Rhode Island: Gov. Gina Raimondo (D) signed an order that loosens coronavirus-related restrictions, effective Feb. 25. Individuals 65 and older are still advised to stay at home as much as possible. Restaurants can provide indoor service at 50 percent capacity. Members from no more than two households can be seated at an indoor table, with a maximum of eight people. If seated outdoors, members of three households per table are allowed. Bar seating can reopen, but no more than two households can be seated at a table, with a maximum of four people. Bar areas must be roped off by 11 p.m. Gyms, athletic facilities and venues of assembly, such as bowling alleys, can allow one person per 125 square feet. Retail stores can permit one person per 100 square feet. Houses of worship can offer indoor and outdoor services at 40 percent capacity, but people from different households must be spaced 6 feet apart. Social gatherings must be limited to members from two households if held indoors and three households if held outside. Events with a licensed caterer or at a restaurant are capped at 30 people indoors and 50 people outdoors. At catered events of more than 15 people, attendees must be tested for COVID-19 before the occasion, and there must be a designated coronavirus safety officer. Anyone arriving in Rhode Island for nonwork purposes from an area with a high community COVID-19 rate must selfquarantine for 10 days or obtain a negative coronavirus test after arrival. Vaccinated individuals are exempt, as long as they received their final dose 14 days before arrival.

Individuals older than 2 must wear a face covering in public spaces, whether indoors or outdoors, if social distancing cannot be maintained. Face masks are also required when using taxis, ride-hailing services or similar transportation options.

- South Carolina: Gov. Henry McMaster (R) announced that he will issue an order lifting restrictions on alcohol sales. Effective March 1, eateries can serve alcohol after 11 p.m. They can operate at 100 percent capacity, but patrons must wear a face covering when inside except when they are eating or drinking. Tables must be spaced at least 6 feet apart. McMaster also stated that he is lifting restrictions on large gatherings. He recommends limiting attendance to 50 percent of a venue's capacity or 250 people. Masks are required at large get-togethers. Other nonessential businesses can reopen; guidelines are recommended. Beaches are open, but the governor has authorized local authorities to close or restrict public access points if it's necessary to protect visitors' health.
- South Dakota: Gov. Kristi Noem signed an order putting the state's "Back to Normal" plan in effect. The plan encourages employers to sanitize high-traffic areas and screen employees for illness. Retail businesses should operate in a manner that promotes social distancing and should consider limiting the number of customers inside their stores. The plan also encourages, but doesn't require, older adults and other vulnerable individuals to stay at home.
- Tennessee: Gov. Bill Lee (R) signed an order that gives local authorities permission to extend mask mandates. Lee has encouraged people to wear masks but stopped short of requiring them. Local authorities can issue a face mask requirement. Previously, Lee lifted many coronavirus-related restrictions for businesses and gatherings in 89 counties. The state's other six counties are subject to the restrictions of their health departments. Effective Feb. 1, the governor lifted restrictions on youth sporting events. Effective Feb. 28, the health department lifted restrictions on long-term care facilities.
- Texas: Gov. Greg Abbott (R) issued an order rolling back reopening plans in counties with a high COVID-19 hospitalization rates. Most businesses in areas with large numbers of hospitalizations must limit occupancy to 50 percent capacity. Abbott's order also closes bars and suspends elective medical procedures in those areas. In areas with a low number of COVID-19 cases, most businesses can operate at 75 percent capacity. Religious services, local government operations and recreational sports programs are among organizations with no occupancy limits. Personal care establishments, such as barbershops and nail salons, also don't have limits on the number of customers; however, there must be a 6-foot distance between workstations, among other precautions.

  Anyone 10 or older must wear a mask in indoor public spaces or when outside if a 6-foot distance from others cannot be maintained. Counties with no more than 20 active COVID-19 cases can apply for an exemption. Gatherings of more than 10

people are prohibited in most circumstances unless local government officials approve them.

- Utah: Former Gov. Gary Herbert (R) lifted a ban that prohibits restaurants from serving alcohol after 10 p.m. A mask mandate remains in effect. Individuals over age 2 must wear a mask and socially distance from non-household members when in an indoor public setting. People over age 2 must also wear a mask when outdoors if within 6 feet of a person from another household. Masks aren't required when an individual is actively eating or drinking, exercising outdoors or exercising indoors if not within 6 feet of a non-household member, among other exceptions. A previous order on gathering limits has expired and was not renewed. All businesses can reopen if they take precautions.
- **Vermont:** Gov. Phil Scott (R) extended until March 15 tighter coronavirus restrictions. Social gatherings involving multiple households are prohibited for individuals who have not been vaccinated (vaccinated individuals or households may gather with one other household). Bars are closed. Restaurants can continue to operate at 50 percent capacity but can seat only one household per table and must close in-person dining by 10 p.m. Takeout and delivery are allowed. Previously, Scott ordered everyone age 2 and older to wear a face covering in public spaces, indoors or outdoors, when physical distancing isn't possible. Hair salons and barbershops can reopen, but they must take appointments and limit occupancy. Hotels, inns, bed-and-breakfasts and other lodging facilities may resume operations on May 22, but all nonessential travelers must follow a self-quarantine mandate. Alternatively, nonessential travelers can quarantine for seven days, followed by a negative COVID-19 test. Travelers who have been vaccinated do not need to quarantine if 14 days have passed since their final dose.
- Virginia: Gov. Ralph Northam (D) permitted a state curfew to expire on Feb. 28. He also loosened coronavirus restrictions on restaurants and gatherings. Effective March 1, eateries can offer indoor service at full capacity but must separate parties by 6 feet and stop serving alcohol at midnight (instead of 10 p.m.). Indoor gatherings will remain capped at 10 people (unless individuals live in the same residence). Outdoor gatherings will be expanded to allow up to 25 people. Indoor and outdoor swimming pools, gyms and fitness centers can operate at 75 percent capacity and follow other guidelines. Movie theaters, concert venues and other entertainment facilities can reopen but must follow strict guidelines. Under a mask mandate, all Virginians 5 and older are required to wear face coverings in indoor spaces shared by others; private residences are exempt.

Individuals must also wear masks outside if social distancing cannot be maintained.

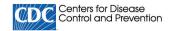
- Washington: Gov. Jay Inslee (D) announced some counties can move to Phase 2 of the state's road to recovery plan. All regions started in Phase 1 on Jan. 11. In Phase 1, indoor social gatherings at private residences are prohibited, and outdoor social gatherings at private residences are limited to 10 people from no more than two households. Restaurants and bars must shutter indoor service. Outdoor dining is permitted, but no more than six people can be seated at a table, and individuals from no more than two households can be seated together. Outdoor dining must close by 11 p.m. Grocery stores, retail stores, places of worship and personal care businesses, such as hair salons, are among places that must restrict occupancy to 25 percent. Gyms and indoor fitness establishments can operate with restrictions, such as training sessions by appointment. In Phase 2, it's permissible to gather indoors with up to 5 people from no more than two households, or outdoors with up to 15 people from no more than two households. Restaurants can reopen indoor dining at 25 percent capacity and can stay open until 11 p.m. Parties are limited to six people from no more than two households. Entertainment venues can operate at 25 percent capacity with a cap of 200 people, and gyms and fitness centers can also operate at 25 percent capacity. Previously, Inslee required masks in indoor public spaces and outdoors when social distancing cannot be maintained.
- West Virginia: Gov. Jim Justice (R) eased COVID-19 restrictions. Effective Feb. 20, restaurants can offer indoor service at 75 percent capacity, with social distancing and other restrictions. Hair salons, gyms, museums and other businesses should follow safety and sanitation protocols. Social gatherings of up to 75 people are permitted. Religious services, weddings or events for essential businesses are among gatherings that are exempt. Previously, Justice revised a statewide mask mandate. Effective Nov. 14, individuals age 9 and older must wear a face covering in all indoor public spaces whether or not social distancing can be maintained. The mandate doesn't apply to people when they are alone in a room, or eating or drinking in a restaurant.
- Wisconsin: After the state legislature voted to repeal Gov. Tony Evers' (D) mask mandate Feb. 4, Evers immediately issued a new one. Everyone age 5 and older must wear a face covering when indoors or in an enclosed space (other than his or her private residence) when other people are present. When outdoors, individuals are encouraged, but not required, to wear masks. Previously, Evers issued a stay-at-home order recommending but not requiring actions

Wisconsinites should take to reduce the spread of COVID-19. Individuals should stay at home. Exceptions include leaving the house to go to work, buy groceries or pick up medications. Businesses should encourage remote work and take precautions where telecommuting isn't possible, such as avoid congregating in conference rooms. For social gatherings, Evers recommended avoiding gettogethers with anyone outside the household.

In May, the Wisconsin Supreme Court struck down the state Department of Health Services' safer-at-home order, issued under Evers' direction. Private businesses can enforce their own restrictions, such as requiring patrons to follow social distancing practices.

• Wyoming: Under the direction of Gov. Mark Gordon (R), the state health officer relaxed coronavirus restrictions on gatherings and removed a health order for personal-care businesses. Effective March 1, indoor and outdoor get-togethers of 50 people in a single, confined space are allowed. If social distancing and other restrictions are in place, indoor events of up to 25 percent of a venue's capacity, with a maximum of 1,000 people, are permitted. Outdoor affairs of up to 50 percent of a venue's capacity, with a maximum of 2,000 attendees, are allowed. Gatherings at hotels, livestock auctions, grocery stores and faith-based organizations are among those that are exempt. The new orders last until March 15. Restaurants, bars and other eateries may offer indoor and outdoor services. Parties are limited to 10 people (larger parties are permitted when individuals live within the same household). The new order lifts the prohibition on buffet services. Gyms must operate with sanitation and other safety measures in place, such as regularly disinfecting workout equipment and locker rooms. Group workout classes are capped at 50 participants. Movie theaters, performance theaters and similar indoor venues may operate, but individual groups must remain 6 feet apart, whether seated or standing in a waiting area. Hair salons and other personal-care businesses may operate without restrictions, but the statewide mask mandate still applies.

Editor's note: This story has been updated to reflect new information.



# Interim Clinical Considerations for Use of mRNA COVID-19 Vaccines Currently Authorized in the United States



Interim considerations: preparing for the potential management of anaphylaxis after COVID-19 vaccination

## Summary of recent changes (last updated February 10, 2021):

- New recommendations for preventing, reporting, and managing mRNA COVID-19 vaccine administration errors (Appendix A).
- Clarification on contraindications and precautions. Persons with a known (diagnosed) allergy to PEG, another mRNA
  vaccine component, or polysorbate, have a contraindication to vaccination. Persons with a reaction to a vaccine or
  injectable therapy that contains multiple components, one of which is PEG, another mRNA vaccine component or
  polysorbate, but in whom it is unknown which component elicited the immediate allergic reaction have a precaution
  to vaccination.
- Updated information on delayed, local injection-site reactions after the first mRNA vaccine dose. These reactions are neither a contraindication or precaution to the second dose.
- Updated quarantine recommendations for vaccinated persons. Fully vaccinated persons who meet criteria will no longer be required to quarantine following an exposure to someone with COVID-19. Additional considerations for patients and residents in healthcare settings are provided.
- Additional information and updated recommendations for testing for TB infection. TB testing can be done before or at the same time as mRNA COVID-19 vaccination, or otherwise delayed for ≥4 weeks after the completion of mRNA COVID-19 vaccination.

# Background

The Advisory Committee on Immunization Practices (ACIP) has issued interim recommendations for the use of Pfizer-BioNTech and Moderna COVID-19 vaccines for the prevention of coronavirus disease 2019 (COVID-19) in the United States. Both vaccines are lipid nanoparticle-formulated, nucleoside-modified mRNA vaccines encoding the prefusion spike glycoprotein of SARS-CoV-2, the virus that causes COVID-19.

These interim CDC clinical considerations are informed by data submitted to the Food and Drug Administration (FDA) for Emergency Use Authorization (EUA) of the vaccines, other data sources, general best practice guidelines for immunization, and expert opinion. These considerations for mRNA vaccines only apply to the currently authorized vaccine products in the United States (i.e., Pfizer-BioNTech and Moderna COVID-19 vaccines). Considerations will be updated when additional information becomes available and/or if additional vaccine products are authorized.

In addition to the following considerations, the EUA conditions of use and storage, handling, and administration procedures described in the prescribing information should be referenced when using the Pfizer-BioNTech and Moderna COVID-19 vaccines.

# Authorized age groups

Under the EUAs, the following age groups are authorized to receive vaccination:

Pfizer-RioNTech: ages > 16 vears

Moderna: ages ≥18 years

Children and adolescents outside of these authorized age groups should not receive COVID-19 vaccination at this time.

# Administration

The mRNA COVID-19 vaccine series consist of two doses administered intramuscularly:

- Pfizer-BioNTech (30 μg, 0.3 ml each): 3 weeks (21 days) apart
- Moderna (100 μg, 0.5 ml): 1 month (28 days) apart

Persons should not be scheduled to receive the second dose earlier than recommended (i.e., 3 weeks [Pfizer-BioNTech] or 1 month [Moderna]). However, second doses administered within a grace period of 4 days earlier than the recommended date for the second dose are still considered valid. Doses inadvertently administered earlier than the grace period should not be repeated.

The second dose should be administered as close to the recommended interval as possible. However, if it is not feasible to adhere to the recommended interval and a delay in vaccination is unavoidable, the second dose of Pfizer-BioNTech and Moderna COVID-19 vaccines may be administered up to 6 weeks (42 days) after the first dose. There are currently limited data on efficacy of mRNA COVID-19 vaccines administered beyond this window. If the second dose is administered beyond these intervals, there is no need to restart the series.

Information on preventing, reporting, and managing mRNA COVID-19 vaccine administration errors is found in Appendix A. Vaccine administration errors should be reported to the Vaccine Adverse Event Reporting System (VAERS) .

# Interchangeability with other COVID-19 vaccine products

Either of the currently authorized mRNA COVID-19 vaccines can be used when indicated; ACIP does not state a product preference. However, these mRNA COVID-19 vaccines are not interchangeable with each other or with other COVID-19 vaccine products. The safety and efficacy of a mixed-product series have not been evaluated. Both doses of the series should be completed with the same product.

Strategies to help ensure that patients receive the second dose with the appropriate product and interval between doses include:

- Providing COVID-19 vaccination record cards to vaccine recipients, asking recipients to bring their card to their
  appointment for the second dose, and encouraging recipients to make a backup copy (e.g., by taking a picture of the
  card on their phone).
- Encouraging vaccine recipients to enroll in VaxText<sup>SM</sup>, a free text message-based platform to receive COVID-19 vaccination second-dose reminders.
- Recording each recipient's vaccination in the immunization information system (IIS).
- Recording vaccine administration information in the patient's medical record.
- Making an appointment for the second dose before the vaccine recipient leaves, to increase the likelihood that patients will present at the same vaccination site for the second dose.

Using the above strategies, every effort should be made to determine which vaccine product was received as the first dose, in order to ensure completion of the vaccine series with the same product. In exceptional situations in which the first-dose vaccine product cannot be determined or is no longer available, any available mRNA COVID-19 vaccine may be administered at a minimum interval of 28 days between doses to complete the mRNA COVID-19 vaccination series. If two doses of different mRNA COVID-19 vaccine products are administered in these situations (or inadvertently), no additional doses of either product are recommended at this time.

Recommendations may be updated when further information becomes available or other vaccine types (e.g., viral vector, protein subunit vaccines) are authorized.

# Coadministration with other vaccines

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Given the lack of data on the safety and efficacy of mRNA COVID-19 vaccines administered simultaneously with other vaccines, the vaccine series should routinely be administered alone, with a minimum interval of 14 days before or after administration with any other vaccine. However, mRNA COVID-19 and other vaccines may be administered within a shorter period in situations where the benefits of vaccination are deemed to outweigh the potential unknown risks of vaccine coadministration (e.g., tetanus toxoid-containing vaccination as part of wound management, rabies vaccination for post-exposure prophylaxis, measles or hepatitis A vaccination during an outbreak) or to avoid barriers or delays to mRNA COVID-19 vaccination (e.g., in long-term care facility residents or healthcare personnel who received influenza or other vaccinations prior to/upon admission or onboarding). If mRNA COVID-19 vaccines are administered within 14 days of another vaccine, doses do not need to be repeated for either vaccine.

# **Booster doses**

The need for and timing of booster doses for mRNA COVID-19 vaccines has not been established. No additional doses beyond the two-dose primary series are recommended at this time.

# Vaccination of persons with a SARS-CoV-2 infection or exposure

Persons with a current or prior history of SARS-CoV-2 infection

Data from clinical trials indicate that mRNA COVID-19 vaccines can safely be given to persons with evidence of a prior SARS-CoV-2 infection. Vaccination should be offered to persons regardless of history of prior symptomatic or asymptomatic SARS-CoV-2 infection. Viral testing to assess for acute SARS-CoV-2 infection or serologic testing to assess for prior infection for the purposes of vaccine decision-making is **not** recommended.

Vaccination of persons with known current SARS-CoV-2 infection should be deferred until the person has recovered from the acute illness (if the person had symptoms) and criteria have been met for them to discontinue isolation. This recommendation applies to persons who experience SARS-CoV-2 infection before receiving any vaccine doses as well as those who experience SARS-CoV-2 infection after the first dose but before receipt of the second dose.

While there is no recommended minimum interval between infection and vaccination, current evidence suggests that the risk of SARS-CoV-2 reinfection is low in the months after initial infection but may increase with time due to waning immunity. Thus, while vaccine supply remains limited, persons with recent documented acute SARS-CoV-2 infection may choose to temporarily delay vaccination, if desired, recognizing that the risk of reinfection, and therefore the need for vaccination, might increase with time following initial infection.

For vaccinated persons who subsequently experience COVID-19, prior receipt of an mRNA COVID-19 vaccine should not affect treatment decisions (including use of monoclonal antibodies, convalescent plasma, antiviral treatment, or corticosteroid administration) or timing of such treatments.

### Persons who previously received passive antibody therapy

Currently, there are no data on the safety and efficacy of mRNA COVID-19 vaccines in persons who received monoclonal antibodies or convalescent plasma as part of COVID-19 treatment. Based on the estimated half-life of such therapies and evidence suggesting that reinfection is uncommon in the 90 days after initial infection, vaccination should be deferred for at least 90 days, as a precautionary measure until additional information becomes available, to avoid potential interference of the antibody therapy with vaccine-induced immune responses. This recommendation applies to persons who receive passive antibody therapy before receiving any vaccine doses and those who receive passive antibody therapy after the first dose but before the second dose, in which case the second dose should be deferred for at least 90 days following receipt of the antibody therapy.

For persons receiving antibody therapies not specific to COVID-19 treatment (e.g., intravenous immunoglobulin, RhoGAM), administration of mRNA COVID-19 vaccines either simultaneously with or at any interval before or after receipt of an antibody-containing product is unlikely to substantially impair development of a protective antibody response. Thus, there is no recommended minimum interval between other antibody therapies (i.e., those that are not specific to COVID-19 treatment) and mRNA COVID-19 vaccination.

Vaccinating persons with a known SARS-CoV-2 exposure or during COVID-19 outbreaks

mRNA vaccines are not currently recommended for outbreak management or for post-exposure prophylaxis, which is vaccination to prevent the development of SARS-CoV-2 infection in a person with a specific known exposure. Because the median incubation period of SARS-CoV-2 is 4–5 days, it is unlikely that the first dose of COVID-19 vaccine would provide an adequate immune response within the incubation period for effective post-exposure prophylaxis. Thus, vaccination is unlikely to be effective in preventing disease following an exposure.

Persons in the community or outpatient setting who have had a known COVID-19 exposure should not seek vaccination until their quarantine period has ended to avoid potentially exposing healthcare personnel and other persons to SARS-CoV-2 during the vaccination visit.

Residents with a known COVID-19 exposure living in congregate healthcare settings (e.g., long-term care facilities), where exposure and transmission of SARS-CoV-2 can occur repeatedly for long periods of time, may be vaccinated. In these settings, healthcare personnel are already in close contact with residents (e.g., entering patient rooms for evaluation and treatment). Vaccinators should employ appropriate infection prevention and control procedures.

Residents of other congregate settings (e.g., correctional and detention facilities, homeless shelters) with a known COVID-19 exposure may also be vaccinated, in order to avoid delays and missed opportunities for vaccination given the increased risk for outbreaks in these settings. However, where feasible, precautions should be taken to limit mixing exposed individuals with other residents or staff (except those essential for the provision of vaccination services, who should employ appropriate infection and control procedures).

Persons residing in congregate settings (healthcare and non-healthcare) who have had an exposure and are awaiting results of SARS-CoV-2 testing may be vaccinated if the person does not have symptoms consistent with COVID-19.

In situations where facility-wide testing is being conducted to identify SARS-CoV-2 infections, facilities should attempt to complete facility-wide testing within a period that allows for test results to be received prior to vaccination in order to isolate those patients with SARS-CoV-2 infection. However, it is not necessary to wait for test results if this would create delays in vaccination. In such situations, persons without symptoms consistent with COVID-19 may be vaccinated. Although not contraindicated, vaccination may be deferred pending outcome of testing in persons with symptoms consistent with COVID-19. Viral testing for acute SARS-CoV-2 infection solely for the purposes of vaccine decision-making is not recommended.

# Vaccination of persons with underlying medical conditions

mRNA COVID-19 vaccines can administered to persons with underlying medical conditions who have no contraindications to vaccination (see 'contraindications' section below). Clinical trials demonstrated similar safety and efficacy profiles in persons with some underlying medical conditions, including those that place them at increased risk for severe COVID-19, compared to persons without comorbidities. Information on groups with specific underlying medical conditions is included below.

### Immunocompromised persons

Persons with HIV infection or other immunocompromising conditions, or who take immunosuppressive medications or therapies might be at increased risk for severe COVID-19. Data are not currently available to establish vaccine safety and efficacy in these groups. Persons with stable HIV infection were included in mRNA COVID-19 vaccine clinical trials, though data remain limited. Immunocompromised individuals can receive COVID-19 vaccination if they have no contraindications to vaccination. However, they should be counseled about the unknown vaccine safety profile and effectiveness in immunocompromised populations, and the potential for reduced immune responses and the need to continue to follow all current guidance to protect themselves against COVID-19 (see below). Antibody testing is not recommended to assess for immunity to COVID-19 following mRNA COVID-19 vaccination.

At this time, re-vaccination is not recommended after immune competence is regained in persons who received mRNA COVID-19 vaccines during chemotherapy or treatment with other immunosuppressive drugs. Recommendations on revaccination or additional doses of mRNA COVID-19 vaccines may be updated when additional information is available.

### Persons with autoimmune conditions

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No data are currently available on the safety and efficacy of mRNA COVID-19 vaccines in persons with autoimmune conditions, though these persons were eligible for enrollment in clinical trials. No imbalances were observed in the occurrence of symptoms consistent with autoimmune conditions or inflammatory disorders in clinical trial participants who received an mRNA COVID-19 vaccine compared to placebo. Persons with autoimmune conditions who have no contraindications to vaccination may receive an mRNA COVID-19 vaccine.

### Persons with a history of Guillain-Barré syndrome

To date, no cases of Guillain-Barré syndrome (GBS) have been reported following vaccination among participants in the Pfizer-BioNTech or Moderna COVID-19 vaccines clinical trials. With few exceptions, ACIP's general best practice guidelines for immunization does not include history of GBS as a contraindication or precaution to vaccination. Persons with a history of GBS may receive an mRNA COVID-19 vaccine unless they have a contraindication to vaccination. Any occurrence of GBS following mRNA COVID-19 vaccination should be reported to VAERS.

### Persons with a history of Bell's palsy

Cases of Bell's palsy were reported following vaccination in participants in both the Pfizer-BioNTech and Moderna COVID-19 vaccines clinical trials. However, the FDA does not consider these to be above the frequency expected in the general population and has not concluded that these cases were causally related to vaccination. Post-authorization safety surveillance will be important to further assess any possible causal association. In the absence of such evidence, persons with a history of Bell's palsy can receive an mRNA COVID-19 vaccine unless they have a contraindication to vaccination. Any occurrence of Bell's palsy following mRNA COVID-19 vaccination should be reported to VAERS.

### Persons with a history of dermal filler use

Infrequently, persons who have received dermal fillers might experience swelling at or near the site of filler injection (usually face or lips) following administration of a dose of an mRNA COVID-19 vaccine. This appears to be temporary and can resolve with medical treatment, including corticosteroid therapy. mRNA COVID-19 vaccines can be administered to persons who have received injectable dermal fillers who have no contraindications to vaccination (see 'contraindications' section below). No additional precautions are needed. However, these persons should be advised to contact their healthcare provider for evaluation if they experience swelling at or near the site of dermal filler following vaccination.

# Vaccination of pregnant or lactating people

### Pregnant people

Observational data demonstrate that while the absolute risk is low, pregnant people with COVID-19 have an increased risk of severe illness, including illness resulting in intensive care admission, mechanical ventilation, or death. Additionally, they might be at an increased risk of adverse pregnancy outcomes, such as preterm birth.

There are currently few data on the safety of COVID-19 vaccines, including mRNA vaccines, in pregnant people. Limited data are currently available from animal developmental and reproductive toxicity studies. No safety concerns were demonstrated in rats that received Moderna COVID-19 vaccine prior to or during gestation in terms of female reproduction, fetal/embryonal development, or postnatal development. Studies in pregnant people are planned and the vaccine manufacturers are following outcomes in people in the clinical trials who became pregnant. Based on current knowledge, experts believe that mRNA vaccines are unlikely to pose a risk to the pregnant person or the fetus because mRNA vaccines are not live vaccines. The mRNA in the vaccine is degraded quickly by normal cellular processes and does not enter the nucleus of the cell. However, the potential risks of mRNA vaccines to the pregnant person and the fetus are unknown because these vaccines have not been studied in pregnant people.

If pregnant people are part of a group that is recommended to receive a COVID-19 vaccine (e.g., healthcare personnel), they may choose to be vaccinated. A conversation between the patient and their clinical team may assist with decisions regarding the use of a mRNA COVID-19 vaccine, though a conversation with a healthcare provider is not required prior to vaccination. When making a decision, pregnant people and their healthcare providers should consider the level of COVID-19 community transmission, the patient's personal risk of contracting COVID-19, the risks of COVID-19 to the patient and potential risks to the fetus, the efficacy of the vaccine, the side effects of the vaccine, and the lack of data about the vaccine during pregnancy.

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Side effects can occur with COVID-19 vaccine use in pregnant people, similar to those expected among non-pregnant people. Pregnant people who experience fever following vaccination can be counseled to take acetaminophen because fever has been associated with adverse pregnancy outcomes. Acetaminophen can be offered as an option for pregnant people experiencing other post-vaccination symptoms.

There is no recommendation for routine pregnancy testing before receipt of a COVID-19 vaccine. Those who are trying to become pregnant do not need to avoid pregnancy after mRNA COVID-19 vaccination.

### Lactating people

There are no data on the safety of COVID-19 vaccines in lactating people or the effects of mRNA COVID-19 vaccines on the breastfed infant or milk production/excretion. mRNA vaccines are not thought to be a risk to the breastfeeding infant. A lactating person who is part of a group recommended to receive a COVID-19 vaccine (e.g., healthcare personnel) may choose to be vaccinated.

# Vaccination of children and adolescents

Adolescents aged 16–17 years are included among persons eligible to receive the Pfizer-BioNTech COVID-19 vaccine under the EUA. While vaccine safety and efficacy data in this age group are limited, there are no biologically plausible reasons for safety and efficacy profiles to be different than those observed in persons 18 years of age and older. Adolescents aged 16–17 years who are part of a group recommended to receive a COVID-19 vaccine may be vaccinated with the Pfizer-BioNTech COVID-19 vaccine with appropriate assent. Children and adolescents younger than 16 years of age are not authorized to receive the Pfizer-BioNTech COVID-19 vaccine at this time.

Children and adolescents younger than 18 years of age are not authorized to receive the Moderna COVID-19 vaccine at this time.

# Patient counseling

### Vaccine efficacy

Preliminary data suggest high vaccine efficacy in preventing COVID-19 following receipt of two doses of mRNA COVID-19 vaccine (Pfizer-BioNTech: 95.0% [95% CI: 90.3%, 97.6%]; Moderna: 94.1% [95% CI: 89.3%, 96.8%]). Limited data are currently available regarding the efficacy of a single dose. Patients should be counseled on the importance of completing the two-dose series with the same vaccine product to optimize protection.

### Reactogenicity

Before vaccination, providers should counsel mRNA COVID-19 vaccine recipients about expected local (e.g., pain, swelling, erythema at the injection site, localized axillary lymphadenopathy on the same side as the vaccinated arm) and systemic (e.g., fever, fatigue, headache, chills, myalgia, arthralgia) post-vaccination symptoms. Depending on vaccine product (Pfizer vs. Moderna), age group, and vaccine dose, approximately 80–89% of vaccinated persons experience at least one local symptom and 55–83% experience at least one systemic symptom following vaccination.

Most systemic post-vaccination symptoms are mild to moderate in severity, occur within the first three days of vaccination, and resolve within 1–3 days of onset. These symptoms are more frequent and severe following the second dose and among younger persons compared with older persons (i.e., ages >55 or ≥65 years [for Pfizer-BioNTech or Moderna vaccines, respectively]). Unless persons experience a contraindication to vaccination (see below), they should be encouraged to complete the series even if they experience local or systemic symptoms following the first dose to optimize protection against COVID-19.

In clinical trials, hypersensitivity-related adverse events were observed in 0.63% of participants who received the Pfizer-BioNTech COVID-19 vaccine and 1.5% of participants who received the Moderna COVID-19 vaccine, compared with 0.51% and 1.1%, respectively, in the placebo groups. Anaphylaxis following vaccination was not observed in the Pfizer-BioNTech or Moderna COVID-19 vaccines clinical trials. However, anaphylactic reactions have been reported following receipt of mRNA vaccines outside of clinical trials.

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Antipyretic or analgesic medications (e.g., acetaminophen, non-steroidal anti-inflammatory drugs) can be taken for the treatment of post-vaccination local or systemic symptoms, if medically appropriate. However, routine prophylactic administration of these medications for the purpose of preventing post-vaccination symptoms is not currently recommended, because information on the impact of such use on mRNA COVID-19 vaccine-induced antibody responses is not available at this time.

In addition, administration of antihistamines to COVID-19 vaccine recipients prior to vaccination to prevent allergic reactions is not recommended. Antihistamines do not prevent anaphylaxis, and their use might mask cutaneous symptoms, which could lead to a delay in the diagnosis and management of anaphylaxis. See section below ("contraindications and precautions to vaccination") and interim considerations for anaphylaxis management for more information on management of anaphylaxis.

Infection prevention and control considerations are available for healthcare personnel and long-term care facility residents (e.g., populations included in phase 1a of vaccine allocation) with systemic signs and symptoms following COVID-19 vaccination. Considerations may be updated as additional information becomes available or additional groups are prioritized for vaccine allocation.

# Contraindications and precautions

While rare, anaphylactic reactions have been reported following vaccination with mRNA COVID-19 vaccines. Although investigations are ongoing, persons with a history of an immediate allergic reaction (of any severity) to an mRNA COVID-19 vaccine or any of its components might be at greater risk for anaphylaxis upon re-exposure to either of the currently authorized mRNA COVID-19 vaccines. For the purposes of this guidance, an immediate allergic reaction to a vaccine or medication is defined as any hypersensitivity-related signs or symptoms such as urticaria, angioedema, respiratory distress (e.g., wheezing, stridor), or anaphylaxis that occur within four hours following administration.

Recommendations for contraindications and precautions are described below and summarized in Appendix B. The following recommendations may change when further information becomes available.

#### Contraindications

CDC considers a history of the following to be a contraindication to vaccination with both the Pfizer-BioNTech and Moderna COVID-19 vaccines:

- Severe allergic reaction (e.g., anaphylaxis) after a previous dose of an mRNA COVID-19 vaccine or any of its components
- Immediate allergic reaction of any severity to a previous dose of an mRNA COVID-19 vaccine or any of its components (including polyethylene glycol [PEG])\*
- Immediate allergic reaction of any severity to polysorbate (due to potential cross-reactive hypersensitivity with the vaccine ingredient PEG)\*

\* These persons should not receive mRNA COVID-19 vaccination (Pfizer-BioNTech or Moderna) at this time unless they have been evaluated by an allergist-immunologist and it is determined that the person can safely receive the vaccine (e.g., under observation, in a setting with advanced medical care available). See Appendix C for more information on ingredients included in mRNA COVID-19 vaccines.

Providers should attempt to determine whether reactions reported following vaccination are consistent with immediate allergic reactions versus other types of reactions commonly observed following vaccination, such as a vasovagal reaction or post-vaccination side effects (which are not contraindications to receiving the second vaccine dose) (Appendix D).

Healthcare personnel or health departments in the United States can request a consultation from the Clinical Immunization Safety Assessment COVIDvax project for a complex COVID-19 vaccine safety question about an individual patient residing in the United States not readily addressed by CDC guidance.

### Precautions

CDC considers a history of any immediate allergic reaction to any other vaccine or injectable therapy (i.e., intramuscular, intravenous, or subcutaneous vaccines or therapies [excluding subcutaneous immunotherapy for allergies, i.e. "allergy shots" not related to a component of mRNA COVID-19 vaccines or polysorbate) as a precaution but not a contraindication to

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vaccination for both the Pfizer-BioNTech and Moderna COVID-19 vaccines. This includes persons with a reaction to a vaccine or injectable therapy that contains multiple components, one of which is PEG, another vaccine component, or polysorbate, but in whom it is unknown which component elicited the immediate allergic reaction.

Persons with a precaution to vaccination should be counseled about the unknown risks of experiencing a severe allergic reaction and balance these risks against the benefits of vaccination. Deferral of vaccination and/or consultation with an allergist-immunologist may be considered until further information on the risk of anaphylaxis is available. The following considerations can be used to help the provider conduct a risk assessment for mRNA COVID-19 vaccination in these individuals:

- Risk of exposure to SARS-CoV-2 (e.g., because of residence in a congregate setting such as a long-term care facility, occupation)
- Risk of severe disease or death due to COVID-19 (e.g., because of age, underlying medical conditions)
- Whether the patient has previously been infected with SARS-CoV-2 and, if so, how long ago
  - Note: Vaccination is recommended for persons with a history of COVID-19; however, because reinfection is
    uncommon in the months following infection, persons with a precaution to vaccination and recent COVID-19 may
    choose to defer vaccination until further information is known about the risk of anaphylaxis following vaccination.
- The unknown risk of anaphylaxis (including fatal anaphylaxis) following mRNA COVID-19 vaccination in a person with a history of an immediate allergic reaction to other vaccines or injectable therapies
- Ability of the patient to be vaccinated in a setting where appropriate medical care is immediately available for anaphylaxis

### Neither contraindications nor precautions to vaccination

Allergic reactions (including severe allergic reactions) not related to vaccines, injectable therapies, components of mRNA COVID-19 vaccines (including PEG), or polysorbates, such as allergic reactions related to food, pet, venom, or environmental allergies, or allergies to oral medications (including the oral equivalents of injectable medications) are **not** a contraindication or precaution to vaccination with either mRNA COVID-19 vaccine. The vial stoppers of these mRNA vaccines are not made with natural rubber latex, and there is no contraindication or precaution to vaccination for persons with a latex allergy. In addition, because the mRNA COVID-19 vaccines do not contain eggs or gelatin, persons with allergies to these substances do not have a contraindication or precaution to vaccination.

Persons with only a delayed-onset local reaction (e.g., erythema, induration, pruritus) around the injection site area after the first vaccine dose do not have a contraindication or precaution to the second dose. Delayed-onset local reactions have been reported in some individuals, including in Moderna clinical trial participants, beginning a few days through the second week after the first dose, and are sometimes quite large. It is not known whether persons who experienced a delayed-onset injection site reaction after the first dose will experience a similar reaction after the second dose. However, these delayed-onset local reactions are not felt to represent a risk for anaphylaxis upon receipt of the second dose. Thus, individuals with such delayed injection site reactions after the first mRNA COVID-19 vaccine dose should receive the second dose using the same vaccine product as the first dose and at the recommended interval, and preferably in the opposite arm.

### Observation periods following vaccination (for persons without contraindications to mRNA COVID-19 vaccines)

CDC recommends an observation period following vaccination with mRNA COVID-19 vaccines. Persons with a history of an immediate allergic reaction of any severity to a vaccine or injectable therapy and persons with a history of anaphylaxis due to any cause should be observed for 30 minutes. All other persons should be observed for 15 minutes.

### Management of anaphylaxis after mRNA COVID-19 vaccination

Appropriate medical treatment used to manage immediate allergic reactions must be immediately available in the event an acute anaphylactic reaction occurs following administration of mRNA COVID-19 vaccine. Further information on anaphylaxis management can be found in the interim considerations for the management of anaphylaxis following COVID-19 vaccination and laboratory evaluation of persons who experience anaphylaxis after vaccination.

# Public health recommendations for vaccinated persons

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While mRNA COVID-19 vaccines have demonstrated high efficacy at preventing severe and symptomatic COVID-19, there is currently limited information on how much the vaccines might reduce transmission and how long protection lasts. In addition, the efficacy of the vaccines against emerging SARS-CoV-2 variants is not known. At this time, vaccinated persons should continue to follow current guidance to protect themselves and others, including wearing a mask, staying at least 6 feet away from others, avoiding crowds, avoiding poorly ventilated spaces, covering coughs and sneezes, washing hands often, following CDC travel guidance, and following any applicable workplace or school guidance, including guidance related to personal protective equipment use or SARS-CoV-2 testing.

However, vaccinated persons with an exposure to someone with suspected or confirmed COVID-19 are not required to quarantine if they meet all of the following criteria<sup>†</sup>:

- Are fully vaccinated (i.e., ≥2 weeks following receipt of the second dose in a 2-dose series, or ≥2 weeks following receipt of one dose of a single-dose vaccine)
- Are within 3 months following receipt of the last dose in the series
- Have remained asymptomatic since the current COVID-19 exposure

Persons who do not meet all 3 of the above criteria should continue to follow current quarantine guidance after exposure to someone with suspected or confirmed COVID-19.

Although the risk of SARS-CoV-2 transmission from vaccinated persons to others is still uncertain, vaccination has been demonstrated to prevent symptomatic COVID-19; symptomatic and pre-symptomatic transmission is thought to have a greater role in transmission than purely asymptomatic transmission. Additionally, individual and societal benefits of avoiding unnecessary quarantine may outweigh the potential but unknown risk of transmission, and facilitate the direction of public health resources to persons at highest risk for transmitting SARS-CoV-2 to others. This recommendation to waive quarantine for people with vaccine-derived immunity aligns with quarantine recommendations for those with natural immunity, which eases implementation.

Fully vaccinated persons who do not quarantine should still watch for symptoms of COVID-19 for 14 days following an exposure. If they experience symptoms, they should be clinically evaluated for COVID-19, including SARS-CoV-2 testing, if indicated. In addition, vaccinated persons should continue to follow current guidance to protect themselves and others, including all other SARS-CoV-2 testing recommendations and requirements, and state, territorial, tribal, and local travel recommendations or requirements. For additional considerations regarding quarantine or work restrictions for fully vaccinated healthcare personnel, patients, or residents in healthcare settings, please see section below.

These quarantine recommendations for vaccinated persons, including the criteria for timing since receipt of the last dose in the vaccination series, will be updated when more data become available and additional COVID-19 vaccines are authorized.

<sup>†</sup> CDC has not systematically evaluated the efficacy of COVID-19 vaccines from manufacturers that have not sought an EUA in the United States. For the purposes of these quarantine criteria, considerations for accepting a vaccination series that is not FDA-authorized include whether the vaccine product has received emergency approval from the World Health Organization or authorization from a national regulatory agency.

### Vaccinated healthcare personnel, patients, and residents in healthcare settings

These criteria could also be applied when considering work restrictions for fully vaccinated healthcare personnel with higher-risk exposures, as a strategy to alleviate staffing shortages. Of note, exposed healthcare personnel would not be required to quarantine outside of work.

As an exception to the above guidance no longer requiring quarantine for fully vaccinated persons, vaccinated inpatients and residents in healthcare settings should continue to quarantine following an exposure to someone with suspected or confirmed COVID-19; outpatients should be cared for using appropriate Transmission-Based Precautions. This exception is due to the unknown vaccine effectiveness in this population, the higher risk of severe disease and death, and challenges with social distancing in healthcare settings. Although not preferred, healthcare facilities could consider waiving quarantine for vaccinated patients and residents as a strategy to mitigate critical issues (e.g., lack of space, staff, or PPE to safely care for exposed patients or residents) when other options are unsuccessful or unavailable. These decisions could be made in consultation with public health officials and infection control experts.

CDC's healthcare infection control guidance contains additional considerations regarding the need to protect healthcare personnel, patients, and residents while also alleviating any staffing shortages.

# Reporting of vaccine adverse events

Adverse events that occur in a recipient following mRNA COVID-19 vaccination should be reported to VAERS. Vaccination providers are required by the Food and Drug Administration to report the following that occur after mRNA COVID-19 vaccination under Emergency Use Authorization:

- Vaccine administration errors
- · Serious adverse events
- · Cases of Multisystem Inflammatory Syndrome
- Cases of COVID-19 that result in hospitalization or death

Reporting is encouraged for any other clinically significant adverse event even if it is uncertain whether the vaccine caused the event. Information on how to submit a report to VAERS is available at https://vaers.hhs.gov \(\sigma\) or by calling 1-800-822-7967.

In addition, CDC has developed a new, voluntary smartphone-based tool, v-safe. This tool uses text messaging and web surveys to provide near real-time health check-ins after patients receive COVID-19 vaccination. Reports to v-safe indicating a medically significant health impact, including pregnancy, are followed up by the CDC/v-safe call center to collect additional information to complete a VAERS report, if appropriate.

# Laboratory testing

Interpretation of SARS-CoV-2 test results in vaccinated persons

Prior receipt of an mRNA COVID-19 vaccine will not affect the results of SARS-CoV-2 viral tests (nucleic acid amplification or antigen tests). Currently available antibody tests for SARS-CoV-2 assess IgM and/or IgG to one of two viral proteins: spike or nucleocapsid. Because both the Pfizer-BioNTech and Moderna COVID-19 vaccines contain mRNA that encodes the spike protein, a positive test for spike protein IgM/IgG could indicate either prior infection or vaccination. To evaluate for evidence of prior infection in an individual with a history of mRNA COVID-19 vaccination, a test specifically evaluating IgM/IgG to the nucleocapsid protein should be used. Antibody testing is not currently recommended to assess for immunity to COVID-19 following mRNA COVID-19 vaccination or to assess the need for vaccination in an unvaccinated person.

Use of immune-based tests for tuberculosis infection, such as the tuberculin skin test and interferon-gamma release assay

The mRNA COVID-19 vaccine should not be delayed because of testing for TB infection. Testing for TB infection with one of the immune-based methods, either the tuberculin skin test (TST) or an interferon release assay (IGRA), can be done before or during the same encounter as the mRNA COVID-19 vaccination. When testing with TST or IGRA cannot be done at the same time as mRNA COVID-19 vaccination, these tests should be delayed ≥4 weeks after the completion of mRNA COVID-19 vaccination but generally should not be cancelled.

Patients who have active TB disease or an illness that is being evaluated as active TB disease can receive an mRNA COVID-19 vaccine (note: the presence of a moderate or severe acute illness is a precaution to administration of all vaccines). Whereas a TST or IGRA test is part of a comprehensive evaluation for TB disease, positive TST or IGRA results are not required to diagnose active TB disease .

When considering a tuberculin skin test or interferon-gamma release assay:

- The TST is not expected to have an effect on the safety or the effectiveness of the mRNA COVID-19 vaccine. IGRAs are blood tests and thus do not affect vaccine safety or effectiveness.
- The reliability of a positive TST or IGRA result after mRNA COVID-19 vaccination is expected to be the same as without the vaccination. mRNA COVID-19 vaccination is not expected to cause false positive results from a TB test that is done at the same encounter as or after mRNA COVID-19 vaccination.
- The reliability of a negative TST or IGRA result after mRNA COVID-19 vaccination has not been studied.

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• The TST is not a vaccine. The guidance for separating other vaccines from mRNA COVID-19 vaccination by at least 2 weeks in time does not apply to the TST because the TST is not a vaccine.

When a tuberculin skin test or interferon gamma release assay is required by policy:

- A TST or IGRA to meet administrative requirements, (for example, for healthcare employment or for admission to longterm care), can be done prior to mRNA COVID-19 vaccination or at the same encounter. The mRNA COVID-19 vaccine should not be delayed because of testing for TB infection.
- A TST or IGRA should be deferred until ≥4 weeks after the completion of mRNA COVID-19 vaccination. If testing
  requirements or policies cannot be modified for the COVID-19 pandemic to accept this delay in TST or IGRA testing, it
  should be understood that a false negative TST or IGRA cannot be excluded, and consideration should be given to
  repeating negative TST or IGRA tests at least 4 weeks after the completion of COVID-19 mRNA vaccination. If TST was the
  initial test, boosting could be a factor if the result of the repeat test is positive.

When a tuberculin skin test or interferon gamma release assay is indicated for medical care:

- The decision as to whether a TST or IGRA that is being done for medical diagnosis ☐ of latent TB infection, (for example, during a contact investigation after exposure to contagious TB disease) should be delayed for 4 weeks after completion of COVID-19 mRNA vaccination is at the discretion of the responsible medical provider and local tuberculosis program overseeing the contact investigation. Medical providers and local tuberculosis programs may not wish to delay testing for persons at high risk for progression to TB disease. However, patients who have a negative result in this context should be considered for retesting ≥4 weeks after the completion of mRNA COVID-19 vaccination.
- Patients who have symptoms or diagnostic findings consistent with active TB disease should receive further medical
  evaluation, for example, with chest radiography and sputum bacteriology for *Mycobacterium tuberculosis*, regardless of
  TST or IGRA results.

# Appendix A. Vaccine administration errors and deviations

A vaccine administration error is any preventable event that may cause or lead to inappropriate use of vaccine or patient harm. This appendix provides resources for preventing and reporting mRNA COVID-19 vaccine administration errors, as well as actions to take after an error has occurred. For completeness, this includes additional scenarios that deviate from CDC recommendations for vaccine intervals but are not considered administration errors. This document is intended to assist providers with handling exceptional situations in which a vaccination error or deviation has already occurred and may be updated when additional information becomes available.

The FDA-issued Emergency Use Authorization and Fact Sheet for Healthcare Providers Administering Vaccines : should be referenced for detailed information on storage and handling, dosing and schedule, dose preparation, and administration of mRNA COVID-19 vaccines. The information provided below on managing vaccine administration errors should not be interpreted as a recommendation or promotion of unauthorized use of the vaccines.

For all vaccine administration errors:

- · Inform the recipient of the vaccine administration error.
- Consult with the state immunization program and/or Immunization Information System (IIS) to determine how the dose should be entered into the IIS, both as an administered dose and to account for inventory.
- Report the error to the Vaccine Adverse Event Reporting System (VAERS), unless otherwise indicated in the table. Providers are required to report all COVID-19 vaccine administration errors—even those not associated with an adverse event to the VAERS. To file an electronic report, please see the VAERS website ...
- Determine how the error occurred and implement strategies to prevent it from happening again. A discussion on
  strategies to prevent errors can be found in the Vaccine Administration chapter of the Epidemiology and Prevention of
  Vaccine-Preventable Diseases (Pink Book). Additional resources can be found on CDC's vaccine administration web page,
  including a job aid for preventing errors.

Type Administration erro	/deviation Interim recommendatio	
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Туре	Administration error/deviation	Interim recommendation
Site/route	<ul> <li>Incorrect site (i.e., site other than the deltoid muscle [preferred site] or anterolateral thigh [alternate site])</li> </ul>	• Do <b>not</b> repeat dose.*
	Incorrect route (e.g., subcutaneous)	• Do <b>not</b> repeat dose.*
Age	Unauthorized age group	<ul> <li>If received first dose at age less than 16 years, do not give second dose at this time∞.</li> <li>If age 16 to 17 years and Moderna vaccine inadvertently administered instead of Pfizer-BioNTech as the first dose, may administer Moderna vaccine as the second dose (as off-label use, because Moderna vaccine is not authorized in this age group).</li> </ul>
Intervals	<ul> <li>Second dose administered fewer than 17 days (Pfizer-BioNTech) or fewer than 24 days (Moderna) after the first dose (i.e., administered earlier than the 4-day grace period)</li> </ul>	• Do <b>not</b> repeat dose.
	<ul> <li>Second dose administered more than 42 days after the first dose</li> </ul>	<ul> <li>Do not repeat dose. This deviation from CDC guidance does not require VAERS reporting.</li> </ul>
	<ul> <li>Dose administered within 14 days before or after another (i.e., non- COVID-19) vaccine</li> </ul>	<ul> <li>Do not repeat COVID-19 vaccine* or other vaccine(s) doses. This deviation from CDC guidance does not require VAERS reporting.</li> </ul>
Mixed series	<ul> <li>Incorrect mRNA COVID-19 vaccine product administered for second dose in 2-dose series</li> </ul>	• Do <b>not</b> repeat dose. §
Dosage	Higher-than-authorized dose volume administered	<ul> <li>Do not repeat dose. *+ Inform the recipient of the potential for local and systemic adverse events.</li> </ul>
	<ul> <li>Lower-than-authorized dose volume administered (e.g., leaked out, equipment failure, recipient pulled away)</li> </ul>	<ul> <li>If more than half of the dose was administered, do not repeat dose.*</li> <li>If less than half of the dose was administered or the proportion of the dose cannot be estimated, administer the authorized dose immediately (no minimum interval) in the opposite arm.#</li> </ul>
Storage and handling	Dose administered after improper storage and handling (e.g., temperature excursion, more than 6 hours after first vial puncture)	<ul> <li>Contact the manufacturer for guidance. If the manufacturer provides information supporting that the dose should be repeated, the repeated dose may be given immediately (no minimum interval) in the opposite arm.</li> </ul>
	Dose administered past the expiration/beyond use date	<ul> <li>Contact the manufacturer for guidance. If the manufacturer provides information supporting that the dose should be repeated, the repeated dose may be given immediately (no minimum interval) in the opposite arm.</li> </ul>

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Туре	Administration error/deviation	Interim recommendation
Diluent (Pfizer- BioNTech only)	ONLY diluent administered (i.e., sterile 0.9% sodium chloride)	Inform the recipient that no vaccine was administered.     Administer the authorized dose immediately (no minimum interval) in the opposite arm.#
,	<ul> <li>No diluent, resulting in higher than authorized dose (i.e., 0.3 ml of undiluted vaccine administered)</li> </ul>	<ul> <li>Do not repeat dose*+ Inform the recipient of the potential for local and systemic adverse events.</li> </ul>
	<ul> <li>Incorrect diluent type (e.g., sterile water, bacteriostatic 0.9% NS)</li> </ul>	<ul> <li>Contact the manufacturer for guidance. If the manufacturer provides information supporting that the dose should be repeated, the repeated dose may be given immediately (no minimum interval) in the opposite arm.</li> </ul>
	<ul> <li>Incorrect diluent volume (i.e., the vial contents were diluted with a diluent volume other than 1.8 ml, but a 0.3 ml dose was still administered)</li> </ul>	<ul> <li>For doses administered with diluent volume less than 1.8 ml, Inform the recipient of the potential for local and systemic adverse events. * †</li> <li>For doses administered with diluent volume greater than 1.8 ml, do not repeat dose. * (Note: dilution with a volume up to 4.0 ml [which exceeds vial capacity] results in more-than-half of the authorized dose administered).</li> </ul>

<sup>\*</sup> If the dose given in error is the first dose, a second dose should be administered at the recommended interval (21 days [Pfizer-BioNTech] or 28 days [Moderna]). If this dose is the second dose, the series is complete and no additional doses are needed.

- <sup>∞</sup> Do not administer the second dose until the person becomes eligible to receive vaccination (either by reaching the authorized age or if the authorization is extended to include additional age groups), even if this results in the second dose being administered after the recommended interval between doses.
- <sup>†</sup> If the administration error resulted in a higher-than-authorized vaccine dose, in general the second dose may still be administered at the recommended interval. However, if local or systemic side effects following vaccination are clinically concerning (outside of the expected side effect profile), lead to serious adverse reactions, or are ongoing at the time of the second dose, the decision to administer the second dose may be assessed on a case-by-case basis.

# Appendix B: Triage of persons presenting for mRNA COVID-19 vaccination

CONTRAINIDICATION TO VACCINIATION	DDECALITION TO VACCINIATION	MANY DROCEED WITH I VA CCINIATION
CONTRAINDICATION TO VACCINATION	PRECAUTION TO VACCINATION	MAY PROCEED WITH VACCINATION

<sup>#</sup> If the dose given in error is the first dose, the second dose should be administered at the recommended interval (21 days [Pfizer-BioNTech] or 28 days [Moderna]) from the date of receipt of the valid dose (not the date of receipt of the erroneous dose).

<sup>§</sup> Although CDC provides considerations for a mixed series in exceptional circumstances, this is still considered an administration error that requires VAERS reporting (as a mixed series is not authorized under the vaccine Emergency Use Authorizations [2]).

CONTRAINDICATION TO VACCINATION

#### PRECAUTION TO VACCINATION

### MAY PROCEED WITH VACCINATION

# ALLERGIES

History of the following are contraindications to Among persons without a contraindication, a receiving either of the mRNA COVID-19 vaccines\*

- Severe allergic reaction (e.g., anaphylaxis) after a previous dose of an mRNA COVID-19 vaccine or any of its components
- Immediate allergic reaction<sup>‡</sup> of any severity to a previous dose of an mRNA COVID-19 vaccine or any of its components<sup>^</sup>(including polyethylene glycol)#
- Immediate allergic reaction of any severity to polysorbate<sup>^#</sup>

history of:

 Any immediate allergic reaction<sup>†</sup> to other vaccines or injectable therapies\*

Among persons without a contraindication or precaution, a history of:

- · Allergy to oral medications (including the oral equivalent of an injectable medication)
- · History of food, pet, insect, venom, environmental, latex, etc., allergies
- · Family history of allergies

# ACTIONS

- Do not vaccinate#
- Consider referral to allergistimmunologist
- Risk assessment
- 30-minute observation period if vaccinated
- Consider deferral of vaccination for further risk assessment and possible referral to allergist-immunologist
- 30-minute observation period: Persons with a history of anaphylaxis (due to any
- 15-minute observation period: All other persons

†Immediate allergic reaction to a vaccine or medication is defined as any hypersensitivity-related signs or symptoms consistent with urticaria, angioedema, respiratory distress (e.g., wheezing, stridor), or anaphylaxis that occur within four hours following administration.

See Appendix B for a list of ingredients. Note: Polyethylene glycol (PEG), an ingredient in both mRNA COVID-19 vaccines, is structurally related to polysorbate and cross-reactive hypersensitivity between these compounds may occur. Information on ingredients of a vaccine or medication (including PEG, a PEG derivative, or polysorbates) can be found in the package insert.

# These persons should not receive mRNA COVID-19 vaccination at this time unless they have been evaluated by an allergistimmunologist and it is determined that the person can safely receive the vaccine (e.g., under observation, in a setting with advanced medical care available)

# Appendix C: Ingredients included in Pfizer-BioNTech and Moderna mRNA COVID-19 vaccines

An immediate allergic reaction to any component or previous dose of an mRNA COVID-19 vaccine is a contraindication to vaccination with both the Pfizer-BioNTech and Moderna vaccines. The following is a list of ingredients for the Pfizer-BioNTech display="1" and Moderna Could Covid-19 vaccines reported in the prescribing information for each vaccine.

Description	Pfizer-BioNTech COVID-19 vaccine	Moderna COVID-19 vaccine
mRNA	Nucleoside-modified mRNA encoding the viral spike (S) glycoprotein of SARS-CoV-2	Nucleoside-modified mRNA encoding the viral spike (S) glycoprotein of SARS-CoV-2
Lipids	2[(polyethylene glycol)-2000]-N,N-ditetradecylacetamide	PEG2000-DMG: 1,2-dimyristoyl-rac-glycerol, methoxypolyethylene glycol
	1,2-distearoyl-sn-glycero-3-phosphocholine	1,2-distearoyl-sn-glycero-3-phosphocholine
	Cholesterol	Cholesterol

14/16

<sup>\*</sup> PEG and polysorbate are common excipients in many vaccines, injectable therapies, and other products. Persons with a known (diagnosed) allergy to PEG, another mRNA vaccine component, or polysorbate, have a contraindication to vaccination. Persons with a reaction to a vaccine or injectable therapy that contains multiple components, one of which is PEG, another mRNA vaccine component or polysorbate, but in whom it is unknown which component elicited the immediate allergic reaction have a precaution to vaccination.

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Description	Pfizer-BioNTech COVID-19 vaccine	Moderna COVID-19 vaccine	
	(4-hydroxybutyl)azanediyl)bis(hexane-6,1-diyl)bis(2-hexyldecanoate)	SM-102: heptadecan-9-yl 8-((2-hydroxyethyl) (6-oxo-6- (undecyloxy) hexyl) amino) octanoate	
Salts,	Potassium chloride	Tromethamine	
sugars, buffers	Monobasic potassium phosphate	Tromethamine hydrochloride	
	Sodium chloride	Acetic acid	
	Dibasic sodium phosphate dihydrate	Sodium acetate	
	Sucrose	Sucrose	

<sup>\*</sup> Neither vaccine contain eggs, gelatin, latex, or preservatives

Note: Both the Pfizer-BioNTech and Moderna COVID-19 vaccines contain polyethylene glycol (PEG). PEG is a primary ingredient in osmotic laxatives and oral bowel preparations for colonoscopy procedures, an inactive ingredient or excipient in many medications, and is used in a process called pegylation to improve the therapeutic activity of some medications (including certain chemotherapeutics). Additionally, cross-reactive hypersensitivity between PEG and polysorbates (included as an excipient in some vaccines and other therapeutic agents) can occur.

Information on whether a medication contains PEG, a PEG derivative, or polysorbates as either active or inactive ingredients can be found in the package insert. The National Institutes of Health DailyMed database can also be used as a resource. As of January 21, 2021, mRNA COVID-19 vaccines are the only currently available vaccines in the United States that contain PEG, though several vaccines contain polysorbate (more information can be found in CDC's vaccine excipient summary ). Some medications that contain PEG and/or polysorbate are also described in the supplementary materials of Stone CA, et al. "Immediate hypersensitivity to polyethylene glycols and polysorbates: more common than we have recognized." The Journal of Allergy and Clinical Immunology: In Practice 7.5 (2019): 1533-1540.

https://www.ncbi.nlm.nih.gov/pmc/articles/PMC6706272/pdf/nihms-1019221.pdf 🔼 🔀

# Appendix D: Potential characteristics of allergic reactions, vasovagal reactions, and vaccine side effects following mRNA COVID-19 vaccination

In patients who experience post-vaccination symptoms, determining the etiology (including allergic reaction, vasovagal reaction, or vaccine side effects) is important to determine whether a person can receive additional doses of mRNA COVID-19 vaccines. The following table of signs and symptoms is meant to serve as a resource but might not be exhaustive, and patients might not have all signs or symptoms. Providers should use their clinical judgement when assessing patients to determine the diagnosis and management.

Characteristic	Immediate allergic reactions (including anaphylaxis)	Vasovagal reaction	Vaccine side effects (local and systemic)
Timing after vaccination	Most occur within 15-30 minutes of vaccination	Most occur within 15 minutes	Median of 1 to 3 days after vaccination (with most occurring the day after vaccination)

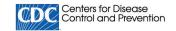
Signs and symptoms

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Characteristic	Immediate allergic reactions (including anaphylaxis)	Vasovagal reaction	Vaccine side effects (local and systemic)
Constitutional	Feeling of impending doom	Feeling warm or cold	Fever, chills, fatigue
Cutaneous	Skin symptoms present in ~90% of people with anaphylaxis, including pruritus, urticaria, flushing, angioedema	Pallor, diaphoresis, clammy skin, sensation of facial warmth	Pain, erythema or swelling at injection site; lymphadenopathy in same arm as vaccination
Neurologic	Confusion, disorientation, dizziness, lightheadedness, weakness, loss of consciousness	Dizziness, lightheadedness, syncope (often after prodromal symptoms for a few seconds or minutes), weakness, changes in vision (such as spots of flickering lights, tunnel vision), changes in hearing	Headache
Respiratory	Shortness of breath, wheezing, bronchospasm, stridor, hypoxia	Variable; if accompanied by anxiety, might have an elevated respiratory rate	N/A
Cardiovascular	Hypotension, tachycardia	Variable; might have hypotension or bradycardia during syncopal event	N/A
Gastrointestinal	Nausea, vomiting, abdominal cramps, diarrhea	Nausea, vomiting	Vomiting or diarrhea might occur
Musculoskeletal	N/A	N/A	Myalgia, arthralgia
Vaccine recommendations			
Recommended to receive 2nd dose of mRNA COVID-19 vaccine?	No	Yes	Yes

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Page last reviewed: February 10, 2021





# COVID-19

# **ACT NOW!**









WEAR A MASK

STAY 6 FEET APART

AVOID CROWDS

# How to Protect Yourself & Others

Updated Feb. 4, 2021

Drint

## Three Important Ways to Slow the Spread

- Wear a mask to protect yourself and others and stop the spread of COVID-19.
- Stay at least 6 feet (about 2 arm lengths) from others who don't live with you.
- Avoid crowds. The more people you are in contact with, the more likely you are to be exposed to COVID-19.

Cases in the last 7 days

458,073



## Wear a mask

- Everyone 2 and older should wear masks in public.
- Masks should be worn in addition to staying at least 6 feet apart, especially around people who don't live with you.
- If someone in your household is infected, people in the household should take precautions including wearing masks to avoid spread to others.
- · Wash your hands or use hand sanitizer before putting on your mask.
- Wear your mask over your nose and mouth and secure it under your chin.
- Fit the mask snugly against the sides of your face, slipping the loops over your ears or tying the strings behind your head.
- If you have to continually adjust your mask, it doesn't fit properly, and you might need to find a different mask type or brand.
- Make sure you can breathe easily.

Effective February 2, 2021, masks are required on planes, buses, trains, and other forms of public transportation traveling into, within, or out of the United States and in U.S. transportation hubs such as airports and stations.



# Stay 6 feet away from others

- Inside your home: Avoid close contact with people who are sick.
  - If possible, maintain 6 feet between the person who is sick and other household members.
- Outside your home: Put 6 feet of distance between yourself and people who don't live in your household.
  - Remember that some people without symptoms may be able to spread virus.

- Stay at least 6 feet (about 2 arm lengths) from other people.
- Keeping distance from others is especially important for people who are at higher risk of getting very sick.

# Avoid crowds

 Being in crowds like in restaurants, bars, fitness centers, or movie theaters put you at higher risk for COVID-19.

# Avoid poorly ventilated spaces

• Avoid indoor spaces that do not offer fresh air from the outdoors as much as possible. If indoors, bring in fresh air by opening windows and doors, if possible.



# Wash your hands often

- Wash your hands often with soap and water for at least 20 seconds especially after you have been in a
  public place, or after blowing your nose, coughing, or sneezing.
- It's especially important to wash:
  - Before eating or preparing food
  - Before touching your face
  - After using the restroom
  - After leaving a public place
  - After blowing your nose, coughing, or sneezing
  - After handling your mask
  - After changing a diaper
  - After caring for someone sick
  - After touching animals or pets
- If soap and water are not readily available, use a hand sanitizer that contains at least 60% alcohol. Cover all surfaces of your hands and rub them together until they feel dry.
- Avoid touching your eyes, nose, and mouth with unwashed hands.



# Cover coughs and sneezes

- Always cover your mouth and nose with a tissue when you cough or sneeze or use the inside of your elbow and do not spit.
- Throw used tissues in the trash.
- Immediately wash your hands with soap and water for at least 20 seconds. If soap and water are not readily available, clean your hands with a hand sanitizer that contains at least 60% alcohol.



## Clean and disinfect

- Clean AND disinfect frequently touched surfaces daily. This includes tables, doorknobs, light switches, countertops, handles, desks, phones, keyboards, toilets, faucets, and sinks.
- If surfaces are dirty, clean them. Use detergent or soap and water prior to disinfection.
- Then, use a household disinfectant. Use products from EPA's List N: Disinfectants for Coronavirus (COVID-19) ☐ according to manufacturer's labeled directions.



# Monitor Your Health Daily

• Be alert for symptoms. Watch for fever, cough, shortness of breath, or other symptoms of COVID-19.

- Especially important if you are running essential errands, going into the office or workplace, and in settings where it may be difficult to keep a physical distance of 6 feet.
- Take your temperature if symptoms develop.
  - Don't take your temperature within 30 minutes of exercising or after taking medications that could lower your temperature, like acetaminophen.
- Follow CDC guidance if symptoms develop.

# Get Vaccinated to Protect Against COVID-19

- COVID-19 vaccination is especially important for people who may be more likely to get very sick from COVID-19, such as older adults and people with certain medical conditions.
- People with underlying medical conditions may get a COVID-19 vaccine as long as they have not had a severe or immediate allergic reaction to the first dose of aCOVID-19 vaccine or any of the ingredients in a COVID-19 vaccine. CDC has made recommendations on who should get vaccinated first.



### Protect Your Health This Flu Season

It's likely that flu viruses and the virus that causes COVID-19 will **both** spread this fall and winter. Healthcare systems could be overwhelmed treating both patients with flu and patients with COVID-19. This means getting a flu vaccine during 2020-2021 is more important than ever.

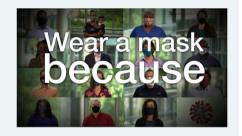
While getting a flu vaccine will not protect against COVID-19 there are many important benefits, such as:

- 1. Flu vaccines have been shown to reduce the risk of flu illness, hospitalization, and death.
- 2. Getting a flu vaccine can also save healthcare resources for the care of patients with COVID-19.

### I wear a mask because...

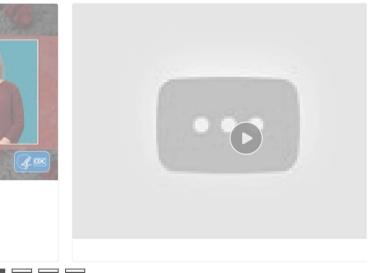
CDC staff give their reasons for wearing a mask.

Wear a mask because...



# Handwashing Resources



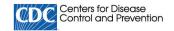




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More information	
Symptoms	Travelers
What to do if you are sick	Individuals, schools, events, businesses and more
If someone in your house gets sick	Healthcare Professionals
Frequently asked questions	

Last Updated Feb. 4, 2021





# COVID-19

# Interim Guidance on Duration of Isolation and Precautions for Adults with COVID-19

Updated Feb. 13, 2021

Print

# **Summary of Recent Changes**

Updates as of February 13, 2021

As of February 13, 2021

- Added new evidence and recommendations for duration of isolation and precautions for severely immunocompromised adults.
- Added information on recent reports in adults of reinfection with SARS-CoV-2 variant viruses.

Accumulating evidence supports ending isolation and precautions for adults with laboratory-confirmed COVID-19 using a symptom-based strategy. This update incorporates recent evidence to inform the duration of isolation and precautions recommended to prevent transmission of SARS-CoV-2 to others, while limiting unnecessary prolonged isolation and unnecessary use of laboratory testing resources. This interim guidance is based upon information available to date and will be updated as new information becomes available.

CDC recommends that all people, regardless of symptoms and regardless of whether or not they have had laboratory-confirmed COVID-19 in the past, continue to use all recommended prevention strategies to prevent SARS-CoV-2 transmission (e.g., wear masks, stay at least 6 feet away from others who do not live with you, avoid crowds, and wash hands regularly).

# **Summary of Key Findings**

- 1. Concentrations of SARS-CoV-2 RNA in upper respiratory specimens decline after onset of symptoms. (39,56,61,63,64,66)
- 2. The likelihood of recovering replication-competent virus also declines after onset of symptoms. For patients with mild to moderate COVID-19, replication-competent virus has not been recovered after 10 days following symptom onset. (1,8,31,36,42,61,66) Recovery of replication-competent virus between 10 and 20 days after symptom onset has been reported in some adults with severe COVID-19; some of these cases were immunocompromised. (56) However, in this series of patients, it was estimated that 88% and 95% of their specimens no longer yielded replication-competent virus after 10 and 15 days, respectively, following symptom onset. Detection of sub-genomic SARS-CoV-2 RNA or recovery of replication-competent virus has been reported in severely immunocompromised patients (e.g., patients with chronic lymphocytic leukemia and acquired hypogammaglobulinemia, lymphoma and immunochemotherapy, hematopoietic stem-cell transplant, chimeric antigen receptor T-cell therapy, or AIDS) beyond 20 days, and as long as 143 days after a positive SARS-CoV-2 test result. (2,67,14,74)

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- 3. In a large contact tracing study, no contacts at high risk of exposure developed infection if their exposure to a case patient started 6 days or more after the case patient's infection onset. (12)
- 4. Recovered patients can continue to have SARS-CoV-2 RNA detected in their upper respiratory specimens for up to 12 weeks after symptom onset. (31,33,34) Investigation of 285 "persistently positive" adults, which included 126 adults who had developed recurrent symptoms, found no secondary infections among 790 contacts to these case patients. Efforts to isolate replication-competent virus from 108 of these 285 case patients were unsuccessful. (31)
- 5. To date, reports of reinfection have been infrequent. Similar to other human coronaviruses where studies have demonstrated reinfection, the probability of SARS-CoV-2 reinfection is expected to increase with time after recovery from initial infection because of waning immunity and the possibility of exposure to virus variants. Circulation of variant viruses (such as the B.1.1.7 variant (20) or B.1.1.28 variant (67,68)) has been reported in several countries. Reinfection with a SARS-CoV-2 variant virus has been reported in Brazil, (69,70,71) the U.K., (72) and South Africa. (73) The risk of reinfection may be increased in the future with exposure to SARS-CoV-2 variant virus strains that are not neutralized by immune antisera, such as one recently described in South Africa. (60) The risk of reinfection also depends on the likelihood of reexposure to infectious cases of COVID-19. Continued widespread transmission makes it more likely that reinfections will occur. Use of prevention strategies can prevent and slow transmission.

### The current evidence includes the following limitations:

- In a study of skilled nursing facility workers followed prospectively for asymptomatic infection, one of 48 staff infected
  with SARS-CoV-2 had a nasopharyngeal swab that was weakly positive on a single-passage plaque assay (and therefore
  contained live virus) more than 20 days after initial diagnosis. However, the specimen was not subjected to serial
  passage to demonstrate the presence of replication-competent virus; (46) in other words, it is not known if the person was
  actually infectious.
- In one case report, an adult with mild illness provided specimens that yielded replication-competent virus for up to 18 days after symptom onset. (34)
- More data are needed concerning viral shedding in some situations, including in immunocompromised adults.
- Data currently available are from adults; comparable data from children and infants on the character of viral shedding or risk for reinfection are not presently available.

# Assessment

### **Duration of Isolation and Precautions**

Available data indicate that adults with mild to moderate COVID-19 remain infectious no longer than 10 days after symptom onset. Most adults with more severe to critical illness or severe immunocompromise likely remain infectious no longer than 20 days after symptom onset; however, there have been several reports of people shedding replication-competent virus beyond 20 days due to severe immunocompromise. (2,6,7,14,74) Recovered adults can continue to shed detectable but non-infectious SARS-CoV-2 RNA in upper respiratory specimens for up to 3 months after illness onset, albeit at concentrations considerably lower than during illness, in concentration ranges where replication-competent virus has not been reliably recovered and infectiousness is unlikely. The circumstances that result in persistently detectable SARS-CoV-2 RNA have yet to be determined. Studies have not found evidence that clinically recovered adults with persistence of viral RNA have transmitted SARS-CoV-2 to others. These findings strengthen the justification for relying on a symptom-based rather than test-based strategy for ending isolation of most patients, so that adults who are no longer infectious are not kept unnecessarily isolated and excluded from work or other responsibilities.

### Role of Viral Diagnostic Testing after Discontinuation of Isolation or Precautions

The duration and robustness of immunity to SARS-CoV-2 remains under investigation. Among other human coronaviruses, reinfection appears to occur variably over time after onset of infection. (19,30) However, for SARS-CoV-2, reinfection appears to be uncommon during the initial 90 days after symptom onset of the preceding infection (Annex: Retesting and Quarantine of Adults Recovered from Laboratory-diagnosed SARS-CoV-2 Infection with Subsequent Re-Exposure). Thus, for adults recovered from SARS-CoV-2 infection, a positive SARS-CoV-2 RT-PCR result without new symptoms during the 90 days after illness onset more likely represents persistent shedding of viral RNA than reinfection.

• If such an adult remains *asymptomatic* during this 90-day period, then any viral retesting is unlikely to yield useful information, even if the adult had close contact with an infected person.

• If such an adult becomes *symptomatic* during this 90-day period, and an evaluation fails to identify a diagnosis other than SARS-CoV-2 infection (e.g., influenza), then the adult likely warrants evaluation for SARS-CoV-2 reinfection in consultation with an infectious disease or infection control expert. Isolation might be warranted before and during this evaluation, particularly if symptoms developed after close contact with an infected person or in association with an outbreak setting. Isolation might also be warranted to prevent transmission of any other potentially transmissible respiratory infections (e.g., that might be confirmed by pending cultures or additional testing).

Correlates of immunity to SARS-CoV-2 infection have not been established. Although a positive serologic test result may indicate resolving or previous infection, a positive test result is unlikely to indicate the onset of acute infection in lieu of a positive viral test result except in rare circumstances (i.e., a positive serologic test result 7 days to 3 weeks following acute illness onset in adults with a previous negative serologic test result). Therefore, only under a rare circumstance such as the one described could a serologic test be used to establish a diagnosis date for the purposes of assessing both the interval between past diagnosis and any new exposure and whether or not testing is indicated.

CDC will continue to closely monitor the evolving science for information that would warrant reconsideration of these recommendations.

# Recommendations

### 1. Duration of isolation and precautions

- For most adults with COVID-19 illness, isolation and precautions can be discontinued 10 days *after symptom onset*\* and after resolution of fever for at least 24 hours, without the use of fever-reducing medications, and with improvement of other symptoms.
  - Some adults with severe illness may produce replication-competent virus beyond 10 days that may warrant
    extending duration of isolation and precautions for up to 20 days after symptom onset; severely
    immunocompromised patients\*\* may produce replication-competent virus beyond 20 days and require
    additional testing and consultation with infectious diseases specialists and infection control experts.
- For adults who never develop symptoms, isolation and other precautions can be discontinued 10 days *after the date of their first positive RT-PCR test result for SARS-CoV-2 RNA*.

### 2. Role of viral diagnostic testing (RT-PCR or antigen)\*\*\* to discontinue isolation or precautions

- For adults who are severely immunocompromised, a test-based strategy could be considered in consultation with infectious diseases experts.
- For all others, a test-based strategy is no longer recommended except to discontinue isolation or precautions earlier than would occur under the strategy outlined in Part 1, above.

### 3. Viral diagnostic testing (RT-PCR or antigen)\*\*\* and quarantine after discontinuation of isolation or precautions

- For adults previously diagnosed with symptomatic laboratory-confirmed COVID-19 who remain asymptomatic after recovery, retesting or quarantine is not recommended if another exposure occurs or might have occurred within 90 days after the date of symptom onset from the initial SARS-CoV-2 infection.
- For adults who develop new symptoms consistent with COVID-19 during the 90 days after the date of initial symptom onset, if an alternative etiology cannot be readily identified by a healthcare provider, then the adult likely warrants retesting. Consultation with infectious disease or infection control experts is recommended, especially in the event that symptoms develop within 14 days after close contact with a person infected with SARS-CoV-2. Adults being evaluated for reinfection with SARS-CoV-2 or any potentially transmissible respiratory infection should be isolated under recommended precautions before and during evaluation. If reinfection is confirmed or remains suspected, they should remain under the recommended SARS-CoV-2 isolation period until they meet the criteria for discontinuation of precautions for most adults, this would be 10 days after symptom onset and after resolution of fever for at least 24 hours, without the use of fever-reducing medications, and with improvement of other symptoms.
- For adults with past laboratory-confirmed SARS-CoV-2 who have never had symptoms and have had a subsequent exposure or possible exposure, the date of first positive viral diagnostic test result (RT-PCR or antigen) for SARS-CoV-2 should be used in place of the date of symptom onset to determine the interval between past infection and the recent exposure. This interval can then be used to inform decisions about testing for the recent exposure.
- Adults who have a past history of symptoms consistent with COVID-19 but who did <u>not</u> have laboratory confirmation of COVID-19 with a viral diagnostic test (RT-PCR or antigen) and who present with new symptoms consistent with COVID-19 should be tested and undergo quarantine.

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• For children and infants, the data pertaining to the risk of reinfection within 90 days following laboratory-confirmed diagnosis are extremely limited. However, in the context of a pandemic, children and infants should be managed as recommended for adults above. CDC will continue to monitor closely the evolving science for information that would warrant reconsideration of these recommendations for this population.

### 4. Role of serologic testing

- Although serologic testing indicating the presence of SARS-CoV-2 antibodies may signify resolving or previous
  infection, it should not generally be used to establish the presence or absence of acute SARS-CoV-2 infection. In
  addition, the date of a positive serologic test should not generally be used to determine the start of the 90-day
  period following SARS-CoV-2 infection for which retesting or quarantine is not recommended. However, if no
  positive viral diagnostic test (RT-PCR or antigen) indicating infection is available, a positive serologic test 7 days to 3
  weeks following acute illness onset in an adult with a history of a previous negative serologic test can be used to
  establish the presence of absence of infection and the start date of the 90-day period.
- \* Symptom onset is defined as the date on which symptoms first began, including non-respiratory symptoms.
- \*\* The studies used to inform this guidance did not clearly define severe immunocompromise. For the purposes of this guidance, CDC defines severe immunocompromise as certain conditions, such as being on chemotherapy for cancer, untreated HIV infection with CD4 T lymphocyte count <200, combined primary immunodeficiency disorder, and receipt of prednisone >20mg/day for more than 14 days, that may cause a higher degree of immunocompromise and therefore should inform decisions regarding the duration of isolation. Other factors, such as advanced age, diabetes mellitus, or end-stage renal disease, may pose a much lower degree of immunocompromise and do not clearly affect decisions about duration of isolation. Ultimately, the degree of immunocompromise for the patient is determined by the treating provider, and preventive actions should be tailored to each patient.

# Annex: Interim Guidance on Retesting and Quarantine of Adults Recovered from Laboratory-diagnosed SARS-CoV-2 Infection with Subsequent Re-exposure

Accumulating evidence supports the recommendation that people who have recovered from laboratory-confirmed COVID-19 do not need to undergo repeat testing or quarantine in the case of another SARS-CoV-2 exposure within 90 days of their initial diagnosis. Evidence does not indicate the definitive absence of re-infection during this period, only that risks of potential SARS-CoV-2 transmission from recovered persons are likely outweighed by the personal and societal benefits of avoiding unnecessary quarantine. CDC recommends that all people, regardless of symptoms, and regardless of whether or not they have had laboratory-confirmed COVID-19 in the past, continue to use all recommended prevention strategies to prevent SARS-CoV-2 transmission (e.g., wear masks, stay at least 6 feet away from others who do not live with you, avoid crowds, and wash hands regularly). This interim guidance is based upon information available to date and will be updated as new information becomes available.

### Summary of Key Findings:

- 1. There are few overall reports of reinfection that have been confirmed through the detection of phylogenetic differences between viruses isolated during the initial and reinfection episodes. Some of these reports demonstrate reinfection occurring at least 90 days after infection onset, (15,21,23,50,54,55) although other reports suggest that reinfection is possible as early as 45 days after infection onset. (4,32,41,44,52,53)
- 2. An increasing number of published studies suggest that >90% of recovered COVID-19 patients develop anti-SARS-CoV-2 antibodies. (17,22,28,57-58) Additional studies also demonstrate antibody response, including neutralizing antibodies and antibody response following mild or asymptomatic infection, can be durable for 6 months or more. (13,16,24,43) This evidence must be interpreted cautiously, as anti-SARS-CoV-2 antibodies have not been definitively correlated with protection from SARS-CoV-2 infection, and it is unclear what antibody titer would be associated with protection.
- 3. Some studies have also noted lower titers and faster waning of anti-SARS-CoV-2 antibodies in mild or asymptomatic cases of COVID-19. (26,35,40,43,49,51,59)
- 4. It is important to note that antibodies are only one component of human immunity and that immunity may be achieved through other mechanisms such as virus-specific memory T and B cells. (10,29,47,48) Studies suggest that the memory T and B cell response can be durable for 6 months or more. (16,24,65) However, one study found that T cell responses were 50% bigher among symptomatic adults as the months post infection. (65)

<sup>\*\*\*</sup> RT-PCR testing is defined as the use of an RT-PCR assay to detect the presence of SARS-CoV-2 RNA.

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5. Animal challenge studies with SARS-CoV-2 (11,18) and investigations of seropositive adults in outbreak settings (5,45) provide initial evidence of protection against reinfection after prior infection with SARS-CoV-2. Serological surveys have also provided evidence linking antibody presence to protection against reinfection, (4,25,37) and an additional animal challenge study demonstrated that exogenously administered anti-SARS-CoV-2 antibodies protected against reinfection in a dose-dependent manner. (38)

### Assessment

Despite millions of SARS-CoV-2 infections worldwide, including the United States, to date, surveillance and investigations have thus far demonstrated few confirmed cases of reinfection. Currently, it is unknown if recovered adults are definitively immune to SARS-CoV-2 reinfection because biologic markers of immunity have not been correlated with protection from infection. However, available evidence suggests that most recovered adults would have a degree of immunity for at least 90 days following initial diagnosis of laboratory-confirmed COVID-19. If the present guidance is implemented with current prevention strategies to prevent SARS-CoV-2 transmission (i.e., wear masks, stay at least 6 feet away from others who do not live with you, avoid crowds, and wash hands regularly), the risks of potential SARS-CoV-2 transmission from recovered adults is generally too low to justify retesting and quarantine.

However, there could be scenarios in which the risk of reinfection and potential transmission may be deemed high enough to warrant retesting and quarantine of the exposed individual who has recovered from laboratory-confirmed SARS-CoV-2 infection; this can include settings where there is low tolerance for introduction of SARS-CoV-2, such as certain congregate settings.

Circulation of variant viruses (such as the B.1.1.7 variant <sup>(20)</sup> or B.1.1.28 variant <sup>(67,68)</sup>) has been reported in several countries. Reinfection with a SARS-CoV-2 variant virus has been reported in Brazil, <sup>(69,70,71)</sup> the U.K., <sup>(72)</sup> and South Africa. <sup>(73)</sup> The risk of reinfection may be increased in the future with exposure to SARS-CoV-2 variant virus strains that are not neutralized by immune antisera, such as one recently described in South Africa. <sup>(60)</sup> This guidance will be updated as additional evidence emerges regarding the reinfection risk that new variants may pose.

#### Recommendation

If an adult has a new exposure to someone with suspected or confirmed COVID-19 and:

- 1. Has recovered from illness due to laboratory-confirmed (RT-PCR or antigen) SARS-CoV-2 infection and has already met criteria to end isolation, and
- 2. Is within the first 90 days following the onset of symptoms of their initial laboratory-confirmed SARS-CoV-2 infection or within the first 90 days of their first positive SARS-CoV-2 test result if they were asymptomatic during initial infection, and
- 3. Has remained asymptomatic since the new exposure,

then that adult does not require repeat testing or quarantine for SARS-CoV-2 in the context of this new exposure.

If an adult has a new exposure to a person with suspected or confirmed COVID-19 and meets the first two above criteria, but has or develops new symptoms consistent with COVID-19 within 14 days of the new exposure, consultation with a health care provider is recommended, and consultation with infectious disease or infection control experts may be necessary. If an alternative cause of the symptoms cannot be readily identified, retesting for SARS-CoV-2 infection may be warranted. In the absence of clinical evaluation to rule out SARS-CoV-2 reinfection, this adult should be isolated for the duration recommended in the memo above – for most adults, this would be 10 days after symptom onset and after resolution of fever for at least 24 hours, without the use of fever-reducing medications, and with improvement of other symptoms. Transmission-based precautions should be used as currently recommended in adults with suspected respiratory infection.

Among children and infants, data pertaining to the risk of reinfection following laboratory-confirmed diagnosis are extremely limited. However, in the context of a pandemic, children and infants should be managed as recommended for adults above.

There also may be circumstances (such as certain congregate settings) where there is increased concern for SARS-CoV-2 transmission. Under these circumstances, repeat testing for SARS-CoV-2 or quarantine can be considered if a new exposure occurs more than 90 days after recovery from a prior infection. As above, the decision to retest or quarantine should be made in consultation with a healthcare provider; consultation with infectious disease or infection control experts may also be necessary.

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