

## Literature Review: Effectiveness of COVID-19 Vaccination

Prepared for Cal/OSHA by HESIS, OHB/CDPH

### EXECUTIVE SUMMARY

The three COVID-19 vaccines currently available in the United States have been found to be highly effective against infection, hospitalization, and death from COVID-19. Vaccine effectiveness against infection with variants, particularly the Delta variant, has been found to be somewhat lower than the effectiveness that was reported early in the vaccination roll-out, but the vaccines remain highly protective against severe outcomes. In addition, the COVID-19 vaccines have been shown to reduce transmission of infection to others.

### Background

There are three COVID-19 vaccines currently available in the United States with approval or emergency use authorization (EUA) from the U.S. Food and Drug Administration (FDA).<sup>1</sup> COVID-19 vaccination for persons 12 years of age and older is recommended by the Centers for Disease Control (CDC) Advisory Committee on Immunization Practices (ACIP) for the prevention of COVID-19. The Pfizer and Moderna vaccines are mRNA vaccines given as two injections several weeks apart; three injections are recommended for immunocompromised persons. The Johnson & Johnson vaccine is a viral vector vaccine given as a single injection. In general, an individual is considered fully vaccinated two weeks after completion of the one- or two-dose series. This review focuses on the experience with COVID-19 vaccines in adults, with an emphasis on studies of fully vaccinated working-age and non-institutionalized persons.

### Vaccine Efficacy in Clinical Trials

Clinical trials of the authorized COVID-19 vaccines demonstrated high efficacy and favorable safety profiles.<sup>2-4</sup> The Pfizer vaccine was studied at 152 sites worldwide in more than 43,000 participants who were randomized to receive vaccine or placebo.<sup>5</sup> Vaccine efficacy against symptomatic confirmed infection was found to be 95%. Nine of ten participants who developed severe COVID-19 were in the placebo group. Adverse effects of vaccine were characterized by pain at the injection site, fatigue, and headache, with low incidence of serious adverse events.

The Moderna vaccine was studied at 99 U.S. sites in more than 30,000 participants who were randomized to receive vaccine or placebo. The vaccine was found to have an efficacy of 94% against symptomatic confirmed infection.<sup>6</sup> Severe COVID-19 disease occurred in 30 participants, with one death; all participants with severe COVID-19 were in the placebo group. In addition, there appeared to be a protective effect against asymptomatic infection: at the second dose visit, 15 (0.1%) asymptomatic participants in the vaccine group versus 39 (0.3%) in the placebo group were positive for SARS-CoV-2 on surveillance testing. Safety issues were limited to transient local and systemic reactions; severe adverse events were rare.

The Johnson & Johnson vaccine was studied at sites in Latin America, the U.S., and South Africa in over 43,000 participants who were randomized to receive vaccine or placebo.<sup>7</sup> Under the same criteria used in the Pfizer and Moderna trials of illness with onset at least 14 days post-vaccination, vaccine efficacy was found to be 67% against moderate to severe-critical confirmed COVID-19 infection and 77% against severe-critical infection. Vaccine efficacy was somewhat

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higher (85%) for severe-critical infection when illness with onset at least 28 days post-vaccination was considered. Moderate infection was defined as two or more mild symptoms or one or more moderate symptoms or signs, including abnormal oxygen saturation above 93%. Severe-critical infection was defined as one or more severe outcomes, which included respiratory failure, other significant organ dysfunction, intensive care unit (ICU) admission, and death. Adverse effects related to the vaccine were described as mild to moderate and transient. There were 11 venous thromboembolic events in the vaccine group and 3 in the placebo group. Five COVID-19-related deaths were observed, all in the placebo group.

### Real-World Vaccine Effectiveness

Following authorization by the FDA, multiple studies demonstrated high effectiveness of these COVID-19 vaccines in the general population outside of clinical trials. An analysis of 136,000 adults in the Mayo Clinic health system who underwent PCR testing for COVID-19 between December 2020 and April 2021 found effectiveness against infection of 86% for the Pfizer vaccine and 93% for the Moderna vaccine.<sup>8</sup> Both vaccines were 100% effective against ICU admission. In a case-control study of about 1,000 adults in California tested for COVID-19 between February 24 and April 29, 2021, vaccine effectiveness was 87% for the Pfizer vaccine and 86% for the Moderna vaccine.<sup>9</sup> When the two vaccines were considered together, effectiveness against symptomatic infection was 91% and against asymptomatic infection was 68%.

Other studies in the U.S. and internationally that examined mRNA vaccine effectiveness during comparable time periods reported similar results. In studies of the general population, mRNA vaccine effectiveness ranged from 80% to 99%, depending on the setting and outcome examined.<sup>10-28</sup> Estimates of vaccine effectiveness were generally lower for asymptomatic infection and mild infection compared to more severe outcomes such as hospitalization and death.

The effectiveness of the mRNA vaccines also was found to be high in healthcare workers during this time, ranging from 80% to 96%.<sup>29-38</sup>

Real-world data on the Johnson & Johnson vaccine are more limited. The vaccine was estimated to be 77% effective against infection in a study of nearly 25,000 adults in the Mayo Clinic health system between February and April 2021.<sup>39</sup> A study that included 456 adults who had received the Johnson & Johnson vaccine documented effectiveness of 68% against hospitalization and 74% against emergency department or urgent care visit.<sup>14</sup> A study using de-identified claims data of nearly 400,000 individuals who had received the Johnson & Johnson vaccine estimated vaccine effectiveness against observed COVID-19 of 74% to 82% from March to June 2021.<sup>40</sup>

### Vaccine Effectiveness against SARS-CoV-2 Alpha, Beta, and Gamma Variants

Viruses like SARS-CoV-2 continuously evolve as mistakes (genetic mutations) occur during replication.<sup>41</sup> A variant has one or more mutations that differentiate it from the original SARS-

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CoV-2 virus and other variants of SARS-CoV-2. Multiple variants of SARS-CoV-2 have been documented in the U.S. and globally throughout the COVID-19 pandemic.

Studies in Israel, Europe, the United Kingdom, Canada, Qatar, Kuwait, and the U.S. found mRNA vaccine effectiveness against the Alpha variant ranged from 65% to 95% in the general population and healthcare workers, depending on the setting and outcome examined.<sup>12,13,16,19,25,27,34,42-60</sup> Vaccine effectiveness was typically lower against asymptomatic infection and higher against severe outcomes.

In Qatar, investigators documented lower effectiveness of the Pfizer vaccine (75-78%) than the Moderna vaccine (96%) against infection with the Beta variant, but vaccine effectiveness against severe outcomes was high ( $\geq 96\%$ ) for both vaccines.<sup>61-63</sup> Another study in Qatar found mRNA vaccine effectiveness against infection with Alpha and Beta in pregnant women to be 68%.<sup>64</sup> In Canada, mRNA vaccine effectiveness against symptomatic infection was reported as 84-88% when Beta and Gamma were circulating, with effectiveness against severe disease of 95-100%.<sup>13,19</sup> In Israel, vaccine effectiveness against documented infection with Gamma was 79% for Pfizer and 85% for Moderna, with higher estimates against hospitalization.<sup>60</sup>

Less information is available for the Johnson & Johnson vaccine and these variants, although data from the clinical trial provides some insights.<sup>7</sup> During the study, the Beta variant was circulating in South Africa. In South African trial participants, vaccine efficacy against moderate to severe-critical infection was 52% and against severe-critical infection was 73%. A study of household contacts in the Netherlands while Alpha was circulating estimated Johnson & Johnson vaccine effectiveness against infection to be 12%, but the number of contacts who had received that vaccine was small (n=44) and the 95% confidence interval (-71% to 54%) was wide.<sup>65</sup>

### Vaccine Effectiveness against SARS-CoV-2 Delta Variant

A growing number of studies address vaccine effectiveness against the Delta variant. The later emergence of Delta in some settings has made it challenging to differentiate between reduced vaccine effectiveness against Delta specifically and the more general issue of waning immunity to any SARS-CoV-2 virus over time. Both of these factors may have contributed to observed reductions in protection of the vaccines against infection with Delta, but protection against severe outcomes remains high.

In the late winter/spring of 2021, effectiveness of the Pfizer vaccine was reported to be 79% in Scotland against infection with Delta, and 87% in Canada and 88% in England against symptomatic infection with Delta.<sup>19,43,49</sup> In late June/early July 2021 in England, when Delta predominated, 2-dose vaccine effectiveness against infection was estimated at 72%.<sup>66</sup> From May to August 2021 in the U.K., Pfizer vaccine effectiveness against documented infection was 80%.<sup>67</sup> In Qatar, vaccine effectiveness for asymptomatic Delta infection was found to be 36% for Pfizer and 80% for Moderna.<sup>68</sup> In Israel during the second half of July 2021, Pfizer vaccine effectiveness against documented infection ranged from 50% to 80% and was inversely related

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to time since vaccination, suggesting waning immunity.<sup>69</sup> A similar pattern was noted in the U.K., where Pfizer vaccine effectiveness against symptomatic Delta infection peaked at 90% two to nine weeks after vaccination, then fell to 70% beyond 20 weeks post-vaccination.<sup>70</sup>

Data from the U.S. confirm these trends. In Minnesota during July 2021, when the Delta variant was predominant, effectiveness against infection was found to be 42% for the Pfizer vaccine and 76% for the Moderna vaccine.<sup>71</sup> Another study set in Minnesota found combined mRNA vaccine effectiveness against asymptomatic infection with primarily Delta variant to be 63%.<sup>16</sup> In Oregon in July 2021, effectiveness against infection for mRNA vaccines was 73% and for the Johnson and Johnson vaccine was 51%.<sup>72</sup> In the Southern California Kaiser Permanente healthcare system through June 2021, Moderna vaccine effectiveness was 73% against asymptomatic infection and 88% against symptomatic infection, with Delta making up 47% of variants among fully vaccinated persons and 11% among unvaccinated persons.<sup>73</sup> Another study in the same healthcare system through early August 2021 found lower Pfizer vaccine effectiveness against infection with Delta (75%) than against other variants (91%) and noted a decline in effectiveness against Delta from 93% during the first month after full vaccination to 53% at four months.<sup>74</sup>

Studies in U.S. healthcare workers also found declining vaccine effectiveness against infection over time. In eight locations across six states, mRNA vaccine effectiveness was 91% during the months preceding Delta predominance and 66% during the Delta predominant period.<sup>75</sup> Similarly, in San Diego, California, mRNA vaccine effectiveness fell from over 90% from March to June 2021 to 66% in July 2021.<sup>76</sup> Notably, in the San Diego study, the attack rate varied by time since vaccination, with a higher attack rate among those vaccinated earlier in the year. This finding suggested both the increasing prevalence of the Delta variant and waning immunity contributed to decrease vaccine effectiveness. Nonetheless, the attack rate among vaccinated healthcare workers remained significantly lower than the attack rate among unvaccinated healthcare workers.

Available data show preserved vaccine effectiveness against severe disease caused by the Delta variant. Studies of mRNA vaccine effectiveness against severe disease or hospitalization while Delta was circulating in the U.K., Israel, Qatar, and Singapore reported estimates of 88-100%.<sup>25,61,68,77-79</sup>

Similar estimates have been documented in the U.S. A study of 13 jurisdictions from April to mid-July 2021, during which Delta prevalence increased from <1% to 90%, found a decrease in crude vaccine effectiveness from 91% to 78% for infection, but smaller changes for more severe outcomes: from 92% to 90% for hospitalization and from 94% to 91% for death.<sup>80</sup> Among New York adults, vaccine effectiveness against infection from May to late July 2021 fell from 92% to 80%, but against hospitalization was stable at 92-95%.<sup>81</sup> In an analysis of data collected from February to August 2021 in five Veteran's Affairs Medical Centers, mRNA vaccine effectiveness against COVID-19 hospitalization was 87% for the entire period and 89% for the period of Delta

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predominance after July 1<sup>st</sup>.<sup>82</sup> Other U.S. studies reported mRNA vaccine efficacy against severe outcomes from Delta infection of 75-93%.<sup>14,47,71,74,78</sup>

In nine U.S. states during June to August 2021, when Delta accounted for >50% of sequenced isolates, vaccine effectiveness against COVID-19 hospitalization was 95% for Moderna, 80% for Pfizer, and 60% for Johnson & Johnson.<sup>83</sup> In this same study, vaccine effectiveness against emergency department and urgent care clinic encounters was 92% for Moderna, 77% for Pfizer, and 65% for Johnson & Johnson. A study comparing the three vaccines at 21 U.S. hospitals across 18 states during March 11–August 15, 2021 estimated vaccine effectiveness against hospitalization to be 93% for Moderna, 88% for Pfizer, and 71% for Johnson and Johnson.<sup>84</sup> In participants who were more than 120 days from full vaccination, effectiveness was somewhat lower for Pfizer at 77% but virtually unchanged for Moderna at 92%. In the study using claims data of individuals who had received the Johnson & Johnson vaccine, vaccine effectiveness during July 2021 against observed COVID-19 was 77% and against COVID-19 hospitalization was 86%.<sup>40</sup>

### Vaccines and Transmission

There is growing evidence that COVID-19 vaccines prevent transmission of the SARS-CoV-2 virus from the vaccinated person to others. In Scotland from December 2020 to March 2021, vaccination of health care workers with the Pfizer vaccine or another vaccine (AstraZeneca) that uses similar technology as the Johnson & Johnson vaccine but is not currently available in the U.S. was associated with a decrease in documented cases of Covid-19 among members of their households.<sup>85</sup> The hazard ratio for a household member to become infected was 0.70 for the period beginning 14 days after the first dose and 0.46 for the period beginning 14 days after the second dose. Similar results were found for vaccinated healthcare workers in Finland, where mRNA vaccine effectiveness against infection in unvaccinated household members was 43% for spouses and 33% for children 10 weeks after the first dose.<sup>86</sup> In Israel during the first four months of 2021, the risk of transmission to healthcare workers' household contacts was significantly reduced in Pfizer vaccinated compared to unvaccinated index cases, with a relative risk of 0.22.<sup>87</sup>

Similar results have been seen in household transmission studies of the general population. A study in England examined transmission from vaccinated and unvaccinated persons with COVID-19 in January and February 2021, finding the likelihood of household transmission was approximately 40 to 50% lower in households of index patients who had been vaccinated with the Pfizer or AstraZeneca vaccines.<sup>88</sup> In Israel through March 2021, the Pfizer vaccine was estimated to have vaccine effectiveness against transmission to household members of 89%.<sup>89</sup>

An analysis of contact tracing data collected in Belgium during January to June 2021 found that vaccine effectiveness against onwards transmission was 62% for the Pfizer vaccine and 52% for the Moderna vaccine; the Johnson & Johnson vaccine did not significantly reduce onward transmission.<sup>90</sup> A similar study in the Netherlands from February to May 2021 found vaccine effectiveness against transmission to household contacts was 71% for all vaccines, 70% for the

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Pfizer, 88% for Moderna, and 77% for Johnson & Johnson.<sup>65</sup> Vaccine effectiveness against transmission to other close contacts was lower at 22%, perhaps explained by misclassification of the index case and thus transmission from another source.

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