






POSITION STATEMENT

COVID-19 vaccines are effective in people with obesity: A position statement from The Obesity Society

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Abstract

The position statement is issued by The Obesity Society in response to published literature, as well as inquiries made to the Society by patients, providers, Society members, policy makers, and others regarding the efficacy of vaccines in persons with obesity against SARS-CoV-2, the virus that causes COVID-19. The Obesity Society has critically evaluated data from published peer-reviewed literature and briefing documents from Emergency Use Authorization applications submitted by Pfizer-BioNTech, Moderna, and Johnson & Johnson. We conclude that these vaccines are highly efficacious, and their efficacy is not significantly different in people with and without obesity, based on scientific evidence available at the time of publication. The Obesity Society believes there is no definitive way to determine which of these three COVID-19 vaccines is “best” for any weight subpopulation (because of differences in the trial design and outcome measures in the phase 3 trials, elapsed time between doses, and regional differences in the presence of SARS-CoV-2 variants [e.g., South Africa B.1.351 in Johnson & Johnson trial]). All three trials have demonstrated high efficacy against COVID-19–associated hospitalization and death. Therefore, The Obesity Society encourages adults with obesity ≥ 18 years (≥ 16 years for Pfizer-BioNTech) to undergo vaccination with any one of the currently available vaccines authorized for emergency use by the US Food and Drug Administration as soon as they are able.

BACKGROUND

The disease of obesity is a recognized risk factor for increased morbidity (1,2) and mortality (3,4) in persons with COVID-19 subsequent to infection with SARS-CoV-2. In addition, obesity is associated with conditions that are independent risk factors and predictors of mortality from COVID-19, including diabetes and other cardiovascular, cerebrovascular, and pulmonary diseases (5). Because of the increased likelihood of severe disease, hospitalization, and death, the Centers for Disease Control and Prevention (CDC) identified obesity (BMI ≥ 30 kg/m²) as a high-risk medical condition in the COVID-19 pandemic (5). On December 20, 2020, the CDC's Advisory Committee on Immunization Practices recommended that persons aged 16 to 64 years with obesity should be prioritized for vaccination in phase 1c of the phased allocation to provide guidance for federal, state, and local jurisdictions where vaccine supply was limited (6).

Past studies (7–12) that demonstrated associations between obesity and an impaired immune response to vaccines have provoked concerns that SARS-CoV-2 vaccines might not be as effective in people with obesity. However, these assertions have not been substantiated to date (13). Immunological memory, which is the basis for durable protection after vaccination, is complex (14) and not easily assessed by any one type of measure, i.e., antibodies (15). Our understanding of humoral response and protective immunity against COVID-19 and after vaccination is evolving but has not yet been fully elucidated for all individuals, with or without obesity.

SARS-COV-2 VACCINES: A FOCUS ON AVAILABLE EMERGENCY USE AUTHORIZATION DATA

At the time of this statement, there are 8 SARS-CoV-2 vaccines in early (or limited) use and 31 vaccines in phase 3 trials (16). Three of these vaccines (Pfizer-BioNTech, Moderna, and Johnson & Johnson) have been granted Emergency Use Authorization in the United States and they have published data on vaccine efficacy in persons with obesity in peer-reviewed journals (17,18) and briefing documents (19–21) presented to the US Food and Drug Administration (FDA). Vaccine efficacy data for the AstraZeneca ChAdOx1 vaccine, approved in the United Kingdom (22), has been published in peer-reviewed journals (23) but does not have clear vaccine efficacy data in persons with overweight or obesity.

Pfizer-BioNTech BNT162b2 (17,19)

The multinational double-blinded clinical trial using a modified mRNA vaccine (BNT162b2), which encodes the full-length SARS-CoV-2 spike(S) protein and instructs immune cells to make several copies of S protein (24), included more than 43,000 adult participants (≥ 16 years old), who were randomized to receive two doses,

21 days apart, of either vaccine or placebo. The primary outcome was confirmed COVID-19 disease, diagnosed at least 7 days after the second dose. The overall vaccine efficacy against SARS-CoV-2 infection, compared with placebo, was 95.0% (95% CI: 90.0%–97.9%) in >36,000 participants without prior infection, compared with placebo. There were 8 confirmed cases (1 severe case) of COVID-19 in the BNT162b2 group and 162 cases (4 severe cases) in the placebo group. The Emergency Use Authorization was revised on May 10, 2021, to authorize emergency use of Pfizer-BioNTech COVID-19 vaccine for the prevention of COVID-19 for individuals 12 through 15 years of age, as well as for individuals 16 years of age and older. BMI percentile was not available at the time of publication (25).

In subgroup analysis of the 13,218 participants age ≥ 16 with obesity (BMI ≥ 30 ; 31.5% of cohort), vaccine efficacy was 95.4% (95% CI: 86.0%–99.1%) among participants with obesity compared with 94.8% (95% CI: 87.4%–98.3%) among participants without obesity. Further stratification by age revealed similar vaccine efficacy between younger adults (age 16 to 64 years) with obesity (94.9%, 95% CI: 84.4%–99.0%) and older adults (age ≥ 65) with obesity (100.0%, 95% CI: 27.1%–100.0%).

Overall, there were no clinically significant differences in efficacy of the Pfizer-BioNTech vaccine among participants age ≥ 16 with obesity compared with those without obesity.

Moderna mRNA-1273 (18,20)

The randomized, double-blinded, placebo-controlled clinical trial evaluating the efficacy of the mRNA-1273 vaccine, which contains information for the synthesis of the stabilized prefusion form of the SARS-CoV-2 S protein (24), was conducted in multiple US sites and enrolled 30,351 participants (≥ 18 years old) who received a two-dose series of vaccine or placebo, 28 days apart. The primary efficacy end point was symptomatic COVID-19 occurrence diagnosed at least 15 days after receipt of the second dose. The overall vaccine efficacy was 94.1% (95% CI: 89.3%–96.8%) without prior evidence of SARS-CoV-2 infection. There were 196 confirmed cases, 11 in the vaccine group and 185 in the placebo group. In the primary efficacy analysis, 30 severe cases of COVID-19 were reported, all in the placebo group, and 1 resulted in death.

Subgroup analysis among participants with severe obesity (BMI ≥ 40 ; 6.5% of cohort) demonstrated vaccine efficacy of 91.2% (95% CI: 32.0%–98.9%), with only 1 case of severe COVID-19 illness identified among 901 participants with severe obesity, compared with 11 cases among 884 participants in the placebo group with severe obesity. Post hoc analysis reported vaccine efficacy of 95.8% (95% CI: 82.6%–99.0%) for participants with obesity (BMI ≥ 30 ; 34.5% of cohort), with 2 cases in the vaccine group and 46 in the placebo group.

Overall, there were no severe cases, hospitalizations, or deaths attributable to COVID-19 among participants in the vaccine group, and there was no clinically significant difference in vaccine efficacy of the Moderna vaccine among participants with obesity compared with participants without obesity.

Janssen/Johnson & Johnson Ad26.CoV2.S (21)

The randomized, double-blinded, placebo-controlled phase 3 trial to evaluate the replication-incompetent adenovirus serotype 26 (Ad26) vectored vaccine enrolled 39,321 participants (≥ 18 years old) from the United States, Brazil, and South Africa. The efficacy of the vaccine at preventing the primary outcome of molecularly confirmed moderate (i.e., at least two mild symptoms or at least one moderate symptom, e.g., abnormal SpO₂ but $>93\%$ on room air) to severe/critical (e.g., respiratory failure requiring high-flow nasal cannula oxygen or mechanical ventilation) COVID-19 infection in all participants was 66.9% (95% CI: 59.0%-73.4%) for onset at least 14 days after dose 1 and 66.1% (95% CI: 55.0%-74.8%) at least 28 days after dose 1. Updated data released on February 8, 2021, were similar to the initial Emergency Use Authorization, demonstrating vaccine efficacy of 67.4% and 66.2% for onset at least 14 days and at least 28 days after vaccination, respectively.

There were 12,492 participants (28.5% of cohort) with obesity (BMI ≥ 30) in the trial. Vaccine efficacy 14 days after dose 1 was 66.8% (95% CI: 54.1%-76.3%) and 65.9% (95% CI: 47.8%-78.3%) 28 days after dose 1 compared with placebo in participants with BMI ≥ 30 . There were no deaths attributable to COVID-19 in the vaccine group, whereas six of the seven fatalities due to COVID-19 in the placebo group were among participants with obesity.

Overall, the vaccine showed similar protection for participants with obesity compared with individuals without obesity.

AstraZeneca AZD-1222 (22,23)

The randomized, double-blinded, placebo-controlled clinical trials using AZD-1222 (ChAdOx1, AstraZeneca), an adenovirus-vectored vaccine that codes for the S-glycoprotein of SARS-CoV-2, were conducted in adults (≥ 18 years old) in the United Kingdom (phase 2/3 trial, COV002 trial), Brazil (phase 3, COV003), and South Africa. Authorization was granted by the United Kingdom's Medicines and Healthcare Products Regulatory Agency. Baseline demographic data from these two trials varied because of protocol amendments that resulted in changes in the trial methodology. The primary efficacy outcome was molecularly confirmed symptomatic COVID-19 illness diagnosed at least 15 days. Pooled data analysis from phase 2/3 and phase 3 data demonstrated vaccine efficacy of 70.4% (95% CI: 54.8%-80.6%) and 66.7% (95% CI: 57.4%-74.0%) in an interim analysis (November 4, 2020) and an updated analysis (December 7, 2020), respectively, at preventing symptomatic COVID-19 more than 15 days after dose 2. Participants with obesity (BMI ≥ 30) made up 19.4% and 20.3% of each trial cohort, and obesity was the most common comorbid condition.

On March 24, 2021, AstraZeneca reported the primary analysis of the US phase 3 trial of AZD1222 demonstrated statistically significant vaccine efficacy of 76% (95% CI: 68%-82%) in preventing symptomatic COVID-19 and 100% efficacy at preventing COVID-related hospitalization 15 days or more after dose 2 (complete data not released; Emergency Use Authorization not submitted). There were 190 cases of

COVID-19 from the 32,449 participants reported in the primary analysis, with 8 cases of severe COVID-19, all in the placebo group.

This primary safety and efficacy analysis did not provide vaccine efficacy data in persons with obesity (26).

The current vaccine efficacy outcomes in persons with obesity for the three available FDA-approved SARS-CoV-2 vaccines are shown in Table 1.

LIMITATIONS

There are limitations of the available data on vaccine efficacy in persons with obesity. First, there is a lack of information about the relative efficacy in the different subtypes of obesity (e.g., more severe forms of the disease, i.e., BMI ≥ 60 , different patterns of body fat distribution). Second, we are not able to comment on the statistical significance of any differences in vaccine efficacy between groups with and without obesity because formal statistical testing of these differences was not performed for any of the vaccines reported on in this statement. Third, the conclusions drawn from this position statement may not be generalizable to other vaccines currently in development, to different administration regimens, or to the use in different populations with obesity, e.g., defined by race, ethnicity, age, or other criteria. Fourth, there is currently a lack of data in younger aged populations <15 years old with obesity at the time this statement was written.

RECOMMENDATIONS

The available clinical evidence from large, multicenter, global randomized controlled trial studies of the three FDA-approved SARS-CoV-2 vaccines (Pfizer-BioNTech, Moderna, and Johnson & Johnson) demonstrate clear evidence that vaccine efficacy outcomes were not clinically different among individuals with obesity compared with individuals without obesity. All of these trials demonstrated high vaccine efficacy, suggesting the vaccine confers protection against severe illness related to the SARS-CoV-2 virus in individuals ≥ 18 years old (≥ 16 years old for Pfizer-BioNTech).

The Obesity Society strongly recommends the use of these vaccines in persons with obesity and that the criteria used to determine the use of the vaccine in persons with obesity be similar to those without obesity. In addition, The Obesity Society recommends that in the development of care plans for patients with COVID-19, obesity (BMI >30) and severe obesity (BMI ≥ 40) should be included as a significant risk of more severe course and outcome of COVID-19.

The Obesity Society will continue to monitor and evaluate emerging data on vaccine efficacy and, when appropriate, will issue an updated evidence-based position statement at a future time. The following recommendations are currently endorsed by the Society regarding vaccine efficacy in persons with obesity:

1. The Obesity Society has confidence in the FDA-approved vaccine trials and the CDC's Advisory Committee on Immunization

TABLE 1 Vaccine efficacy outcomes in persons with obesity for the three available FDA-approved SARS-CoV-2 vaccines

SARS-CoV-2 vaccine	Number of doses required	Percent of participants with obesity	Overall vaccine efficacy % (95% CI)	Vaccine efficacy % (95% CI) in obesity	Notable findings for obesity
Pfizer-BioNTech BNT162b2	2 (21 days apart)	31.5	95.0 (90.0, 97.9)	95.4 (86.0, 99.1) ^a	Efficacy in younger adults (<64) and older adults (age ≥65) was similar
Moderna mRNA-1273	2 (28 days apart)	34.5 6.5 with BMI ≥40	94.1 (89.3, 96.8)	95.8 (82.6, 99.0) ^b 91.2 (32.0, 98.9) ^c	None found/ reported
Johnson & Johnson Ad26.CoV2.S	1	28.5	66.9 (59.0, 73.4) ^d 66.1 (55.0, 74.8) ^e	66.8 (54.1, 76.3) ^f 65.9 (47.8, 78.3) ^g	Obesity present in 6/7 deaths in placebo group, no deaths in vaccine group

The Phase 3 trials of these FDA-approved SARS-CoV-2 vaccines had different trial designs and outcome measures in different populations. In addition, vaccines were tested at different periods of time during the pandemic, one trial with a large percentage of a SARS-CoV-2 variant (e.g. South Africa B.1.351 in the Johnson & Johnson trial) resulting in the inability to make a direct comparison of the vaccine efficacy in this table.

^aParticipants with obesity (BMI ≥30), 7 days after dose 2, per VRBPAC Briefing Document, December 10, 2020 (19).

^bParticipants with obesity (BMI ≥30), 14 days after dose 2, per VRBPAC Briefing Document, December 17, 2020 (20).

^cParticipants with severe obesity (BMI ≥40), 14 days after dose 2, per VRBPAC Briefing Document, December 17, 2020 (20).

^dAll participants, 14 days after dose 1, per VRBPAC Briefing Document, February 26, 2021 (21).


^eAll participants, 28 days after dose 1, VRBPAC Briefing Document, February 26, 2021 (21).

^fParticipants with obesity (BMI ≥30), 14 days after dose 1, per VRBPAC Briefing Document, February 26, 2021 (21).

^gParticipants with obesity (BMI ≥30), 28 days after dose 1, per VRBPAC Briefing Document, February 26, 2021 (21).

Abbreviation: VRBPAC, Vaccines and Related Biological Products Advisory Committee.

Practices updated interim vaccine allocation recommendations in the indicated US populations, including individuals with obesity and severe obesity.

- The Obesity Society recommends that persons with obesity be vaccinated for prevention of COVID-19, in agreement with CDC recommendations, as obesity is clearly associated with an increased risk of a more severe course of COVID-19 disease and death (6).
- At present, there is no definitive way to determine which COVID vaccine is “best” for patients overall or for specific patient subgroups, including those with obesity. Current FDA-approved COVID-19 vaccines from Pfizer-BioNTech, Moderna, and Johnson & Johnson were all highly efficacious against COVID-19-associated hospitalization and death in trials and were found to be equally efficacious in persons with obesity compared with normal weight individuals. The Obesity Society advises persons with obesity to accept whichever available vaccination is offered.
- Peer-reviewed data do not support a hypothesis of impaired humoral immune responses to the SARS-CoV-2 vaccine in people with obesity.
- Publication of long-term vaccine efficacy outcomes, stratified by obesity status, in peer-reviewed journals is needed and is strongly encouraged. Targeted studies in specific obesity subgroups may enhance our understanding of the efficacy, safety, and optimal use of the vaccines in persons with obesity. 

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CONFLICT OF INTEREST

WSB – Consulting: Rhythm Pharmaceuticals, Novo Nordisk. AMJ – Consulting: Novo Nordisk, Boehringer Ingelheim, Eli Lilly, Intellihealth, Scholar Rock, Pfizer; Research: American Diabetes Association, Eli Lilly, Novo Nordisk. MIC – Employee: WW; Consulting: Novo Nordisk (did not accept personal fees for this work). TKK – Gelesis, Novo Nordisk, Nutrisystem. FCS – Consulting: Calibrate, Novo Nordisk; Research: Amazon. AMJ additionally discloses that her spouse serves as a consultant for Agios, serves on the advisory committee of Pangolin, and is a consultant and scientific cofounder of Elucidata. AMH, WTD, LMZ, and CMK declared no conflict of interest.

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