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Original Research Paper

Medical Science

COMPARISON OF THE SIDE EFFECTS OF THE VARIOUS COVID-19 VACCINES

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ABSTRACT

Purpose: In this paper, we will analyze the side effects of the 4 popular Covid-19 vaccines (Moderna, Pfizer, Johnson & Johnson, AstraZeneca) and compare the population groups involved in each vaccine trial. With the availability of these 4 different vaccines, people are trying to understand the differences in the side effect profile of each vaccine. We have attempted to collect data from the different publicly reported sites which include information about the various trials for each vaccine and pull all the numbers in one place to help the readers compare for themselves.

Method: We collected data relating to the side effects of each vaccine from the Fact Sheet for Health Care Providers EUA published by the FDA for each vaccine as well as data from the Phase 1-2a trial of the AstraZeneca vaccine published by the Lancet.

https://www.fda.gov/media/144637/download
https://www.fda.gov/media/144413/download
https://www.fda.gov/media/146304/download
https://www.thelancet.com/action/showPdf?pii=S0140-6736%2820%2932661-1

Results: The common side effects after the vaccines such as headache, fatigue, nausea, pain, swelling at vaccine site, fever was compared between different vaccine groups as well as between various age subgroups in each vaccine group. Then we focused on the rare side effects associated with each vaccine such as Bell's Palsy with Pfizer and Moderna vaccines and thromboembolic events with J&J vaccine and transverse myelitis in the Astra Zeneca vaccine. The side effect rate in each vaccine and placebo group is included in the data.

Conclusion: In effect all vaccines are found safe with incidence of the rare and serious adverse events being extremely low and, in some cases, extremely difficult to say whether the adverse event could actually be attributed to the vaccine or to chance given the actual incidence of the disease in the general population.

KEYWORDS :

Covid-19, or the Coronavirus Disease has spread globally and has affected every community in some way. This outbreak is believed to have originated in Wuhan, China and the disease is believed to have been transferred from a bat to a human. This, however, is not the origin of this disease as in 2002-2004 there was a SARS outbreak which is believed to have come from racoon dogs. As of now, there have been over 83 million reported cases and over 1.8 million deaths. In the USA alone, there have been over 20 million reported cases and over 350,000 deaths. Statistically, this is the largest pandemic the Earth has ever faced. Recently, however, there has been success in creating a vaccine in order to prevent the spread of Covid-19. Specifically, four different organizations have come up with four different vaccines, one per organization, and executed trials for each vaccine. These four organizations are Pfizer, Moderna, Johnson & Johnson, and AstraZeneca.

In this paper, we will analyze the side effects for each vaccine and compare the population groups involved in each vaccine trial. With the availability of 4 different vaccines people are trying to understand the differences in the side effect profile of each vaccine. We have attempted to collect data from the different publicly reported sites which include information about these various trials and pull all the numbers in one place to help the readers compare for themselves. In order to do this, we will divide the trial groups based on age.

The Pfizer vaccine is an mRNA vaccine, meaning it carries the genetic instruction to enable the cells to produce antibodies to fight Covid-19 by mimicking infection. This vaccine instructs the cell to produce antigens which mimic the COVID-19 viral particles and thus induce the body's immune system to build antibodies against the COVID-19 virus. This vaccine requires two doses 21 days apart and requires storage at -60 degrees Celsius to -80 degrees Celsius. The Moderna vaccine is an mRNA vaccine as well which requires two doses 28 days apart and requires storage at -15 degrees Celsius to -25 degrees Celsius. The Johnson & Johnson vaccine uses an adenovirus as a vector, which creates coronavirus proteins in the body to prepare the immune system to fight Covid-19 and requires a single dose and can be stored from 2 degrees Celsius to 8 degrees Celsius. The AstraZeneca vaccine uses a weakened adenovirus and requires two doses 28 days apart and requires storage from 2 degrees Celsius to 8 degrees Celsius. The Pfizer, Moderna, Johnson & Johnson, and AstraZeneca trials had 43,448 participants, 30,000 participants, 45,000 participants, and 30,000 participants, respectively.

In order to compare the side effects, we begin with the Moderna vaccine. The common side effects for the Moderna vaccine include pain at vaccination site at a rate of 92.0 %, fatigue at a rate of 70.0%, myalgia at a rate of 61.5%, arthralgia at a rate of 46.4%, chills at a rate of 45.4%, nausea/vomiting at a rate of 23.0%, axillary swelling/tenderness at a rate of 19.8%, fever at a rate of 15.5%, swelling at injection site at a rate of 14.7%, and erythema at injection site at a rate of 10.0%. The trial had 30351 participants. The split between groups was 15185 people in the vaccine group and 15166 in the placebo group. The mean age of the group was 52 and the gender split was 52.7% male and 47.3% female. The racial split was 79.2% white, 10.2% African American, and 4.6% Asian. Lymphadenopathy-related events were reported at 1.1% in vaccinated group and 0.6% in placebo group, Hypersensitivity was reported in 1.5% of vaccinated group and 1.1% of placebo group. There were two cases of serious face swelling believed to be associated with use of fillers and one case of nausea requiring hospitalization in the vaccinated group.

Bell's Palsy was reported by three participants in the vaccine group. Onset of paralysis was 22, 28, and 32 days after vaccination. One case in the placebo group 17 days after vaccination. Currently there is not enough information to identify a relationship however no patterns or imbalances suggest a causal relationship between the vaccine and Bell's Palsy.

Now, we move on to the Pfizer vaccine.

The common side effects of the Pfizer vaccine include pain at

injection site at a rate of 84.1%, fatigue at a rate of 62.9%, headache at a rate of 55.1%, muscle pain at a rate of 38.3%, chills at a rate of 31.9%, joint pain at a rate of 23.6%, fever at a rate of 14.2%, injection site swelling at a rate of 10.5%, injection site redness at a rate of 9.5%, nausea at a rate of 1.1%, malaise at a rate of 0.5%, and lymphadenopathy at a rate of 0.3%. There were 21720 participants in the vaccine group vs. 21728 participants in the placebo group and 43448 participants in total. The gender split was 50.6% male and 49.4% female. The race split was 83.1% White, 9.1% Black, 28.0% Hispanic/Latino, 4.3% Asian, and 0.5% American Indian/Alaskan native. Participants between the ages of 16-55 had 0.4% and 0.3% report serious adverse effects for vaccine group vs placebo group. Participants of ages 56+ had 0.8% and 0.6% report serious adverse effects for vaccine group vs placebo group. Participants of ages 16-55 had 29.3% and 13.2% report non serious adverse effects for vaccine group vs placebo group. Participants of ages 56+ had 23.8% and 11.7% report non serious adverse effects for vaccine group vs placebo group.

Bell's Palsy was reported by four participants in the vaccine group. Onset of paralysis was 37 days after Dose 1 and 3, 9, and 48 days after Dose 2. No cases in the placebo group. Currently there is not enough information to identify a relationship however no patterns or imbalances suggest a causal relationship between the vaccine and Bell's Palsy.

Appendicitis reported in 8 members of vaccinated group and 4 members of placebo group. Currently there is not enough information to identify a relationship however no patterns or imbalances suggest a causal relationship between the vaccine and Appendicitis.

Now we move on to the Johnson & Johnson vaccine trial.

There was a total of 43,783 members in the Johnson & Johnson study with 21,895 members receiving the vaccine. 45.0% were female while 54.9% were male. 58.7% were white, 19.4% were black or African American, 45.3% were Hispanic or Latino, 3.3% were Asian, 9.5% were American Indian or Alaskan, 0.2% were Hawaiian or Pacific Islanders, 5.6% were from multiracial group, and 1.4% had unknown races. Urticaria reported in five recipients of vaccine and one recipient of placebo. Hypersensitivity reported in one recipient of the vaccine.

Numerical imbalances, with more events in vaccine than placebo recipients, were observed for the following serious and other adverse events of interest in individuals receiving the vaccine or placebo, respectively:

- Thromboembolic events:
  - Deep vein thrombosis: 6 events (2 serious; 5 within 28 days of vaccination) vs. 2 events (1 serious; 2 within 28 days of vaccination).
  - Pulmonary embolism: 4 events (3 serious; 2 within 28 days of vaccination) vs. 1 event (serious and within 28 days of vaccination).
  - Transverse sinus thrombosis: 1 event (serious and within 28 days of vaccination) vs. 0.
- Seizures: 4 events (1 serious; 4 within 28 days of vaccination) vs. 1 event (0 serious and 0 within 28 days following vaccination).
- Tinnitus: 6 events (0 serious; 6 within 28 days of vaccination, including 3 within 2 days of vaccination) vs. 0.

Finally, we have the AstraZeneca vaccine trial.

For the age group of 18-55, 162 participants were in the Low Dose Group, 158 participants were in the High Dose Group, 82 participants were in the Placebo Group, and there were 402 participants in total. The gender distribution in each group was 78 males to 84 females, 72 males to 85 females, and 40 males to 42 males, respectively. There were 364 white participants, 20 black participants, 10 Asian participants, 17 Hispanic or Latino participants, 1 Hawaiian/pacific islander, 3 American Indian or Alaskan participants, 1 with multiple races, and 3 unknown participants. For the age group of 65+, 161 in Low Dose Group, 161 in High Dose Group, 81 in Placebo Group, and 403 participants in total. The gender distribution in each group was 84 males to 77 females, 79 males to 82 females, and 38 males to 43 males, respectively. There were 397 white participants, 3 black participants, 6 Hispanic or Latino participants, 1 American Indian or Alaskan participant, 1 unknown, and 1 not reported.

There were 175 serious adverse events (84 in the ChAdOx1 nCoV-19 group and 91 in the control group), three of which were possibly related to the intervention: transverse myelitis occurring 14 days after a ChAdOx1 nCoV-19 booster vaccination, hemolytic anemia in a control recipient, and fever higher than 40°C in a participant still masked to group allocation. Two additional transverse myelitis cases considered unlikely to be related to the intervention occurred: one 10 days after the first dose of ChAdOx1 nCoV-19 was attributed to pre-existing multiple sclerosis and one in a control group that occurred 68 days after vaccination. The transverse myelitis cases resulted in temporarily pausing the trial and all participants have recovered or are recovering.

Comparison Of Side Effects After Each Vaccination:

Headache: 41.9% first dose 51.7% second dose for ages 18-55 and 25.2% first dose 39.0% second dose for ages 56+ for Pfizer, 35.3% first dose 62.8% second dose for ages 18-64 and 24.5% first dose 46.2% second dose for ages 65+ for Moderna, 44.4% in ages 18-59 30.4% in ages 60+ for Johnson & Johnson, 45% low dose 70% high dose for ages 18-55 and 30% low dose 35% high dose for ages 65+ for AstraZeneca

Fatigue: 47.4% first dose 59.4% second dose for ages 18-55 and 34.1% first dose 50.5% second dose for ages 56+ for Pfizer, 38.4% first dose 67.6% second dose for ages 18-64 and 33.3% first dose 58.3% second dose for ages 65+ for Moderna, 43.8% in ages 18-59 29.7% in ages 60+ for Johnson & Johnson, 50% low dose 70% high dose for ages 18-55 and 30% low dose 40% high dose for ages 65+ for AstraZeneca

Nausea: No Data for Pfizer, 9.4% first dose 21.4% second dose for ages 18-64 and 5.2% first dose 11.8% second dose for ages 65+ for Moderna, 15.5% in ages 18-59 12.3% in ages 60+ for Johnson & Johnson, 27% low dose 30% high dose for ages 18-55 and 5% low dose 7% high dose for ages 65+ for AstraZeneca

Pain: 83.1% first dose 77.8% second dose for ages 18-55 and 71.1% first dose 66.1% second dose for ages 56+ for Pfizer, 86.9% first dose 89.9% second dose for ages 18-64 and 74.0% first dose 83.2% second dose for ages 65+ for Moderna, 58.6% in ages 18-59 33.3% in ages 60+ for Johnson & Johnson, 63% low dose 77% high dose for ages 18-55 and 40% low dose 40% high dose for ages 65+ for AstraZeneca

Swelling: 5.8% first dose 6.3% second dose for ages 18-55 and 6.5% first dose 7.5% second dose for ages 56+ for Pfizer, 11.6% first dose 16.2% second dose for ages 18-64 and 6.1% first dose 8.5% second dose for ages 65+ for Moderna, 7.0% in ages 18-59 2.7% in ages 60+ for Johnson & Johnson, 2% low dose 3% high dose for ages 18-55 and 5% low dose 5% high dose for ages 65+ for AstraZeneca

Fever: 3.7% first dose 15.8% second dose for ages 18-55 and 1.4% first dose 10.9% second dose for ages 56+ for Pfizer, 0.9% first dose 17.4% second dose for ages 18-64 and 0.3% first dose 10.0% second dose for ages 65+ for Moderna, 12.8%

in ages 18-59 3.1% in ages 60+ for Johnson & Johnson, No data for AstraZeneca

Rare Side Effects in Each Group:

Moderna:
Bell's Palsy 3 in vaccine 1 in placebo

Pfizer:
Bell's Palsy 4 in vaccine 0 in placebo
Appendicitis 8 in vaccine 4 in placebo

Johnson & Johnson:
Thromboembolic events:
Deep vein thrombosis: 6 events (2 serious; 5 within 28 days of vaccination) vs. 2 events (1 serious; 2 within 28 days of vaccination).

Pulmonary embolism: 4 events (3 serious; 2 within 28 days of vaccination) vs. 1 event (serious and within 28 days of vaccination).

Transverse sinus thrombosis: 1 event (serious and within 28 days of vaccination) vs. 0

Other:
Seizures: 4 events (1 serious; 4 within 28 days of vaccination) vs. 1 event (0 serious and 0 within 28 days following vaccination).

Tinnitus: 6 events (0 serious; 6 within 28 days of vaccination, including 3 within 2 days of vaccination) vs. 0.

Update on J & J Vaccine:
Recently, the Johnson and Johnson vaccine trial had been shut down due to cases of thrombosis with thrombocytopenia in those who received the vaccine. There were 15 cases in 7.98 million people vaccinated or 1.9 cases per million people vaccinated. After careful analysis, the Johnson & Johnson vaccine was deemed safe and was reapproved to be administered to people in the United States.

Studies and data collected from Clinical Trials Experience:

In the tables below, we present select data from the various studies conducted from clinical trials of these vaccines, starting with **Pfizer-BioNTech COVID-19 Vaccine**. Because clinical trials are conducted under widely varying conditions, adverse reaction rates observed in the clinical trials of a drug cannot be directly compared to rates in the clinical trials of another drug and may not reflect the rates observed in practice. Also, we have provided the link to the source from where this data is presented so that the readers can get the remainder of the data sets on these studies from that source.

Frequency and Percentages of Participants with Solicited Local Reactions, by Maximum Severity, Within 7 Days After Each Dose – Participants 18 through 55 Years of Age‡ – Reactogenicity Subset of the Safety Population*

https://www.fda.gov/media/144413/download

	Pfizer-BioNTech COVID-19 Vaccine Dose 1 N[a]=2291 n[b] (%)	Placebo Dose 1 N[a] =2298 n[b] (%)	Pfizer-BioNTech COVID-19 Vaccine Dose 2 N[a] = 2098 n[b] (%)	Placebo Dose 2 N[a] = 2103 n[b] (%)
Redness[c]				
Any (>2 cm)	104 (4.5)	26 (1.1)	123 (5.9)	14 (0.7)
Mild	70 (3.1)	16 (0.7)	73 (3.5)	8 (0.4)
Moderate	28 (1.2)	6 (0.3)	40 (1.9)	6 (0.3)
Severe	6 (0.3)	4 (0.2)	10 (0.5)	0 (0.0)
Swelling[c]				
Any (>2 cm)	132 (5.8)	11 (0.5)	132 (6.3)	5 (0.2)
Mild	88 (3.8)	3 (0.1)	80 (3.8)	3 (0.1)
Moderate	39 (1.7)	5 (0.2)	45 (2.1)	2 (0.1)
Severe	5 (0.2)	3 (0.1)	7 (0.3)	0 (0.0)
Pain at the injection site[d]				
Any	1904 (83.1)	322 (14.0)	1632 (77.8)	245 (11.7)
Mild	1170 (51.1)	308 (13.4)	1039 (49.5)	225 (10.7)
Moderate	710 (31.0)	12 (0.5)	568 (27.1)	20 (1.0)
Severe	24 (1.0)	2 (0.1)	25 (1.2)	0 (0.0)

Note: Reactions were collected in the electronic diary (e-diary) from Day 1 to Day 7 after vaccination.
a. N = Number of participants reporting at least 1 yes or no response for the specified reaction after the specified dose.
b. n = Number of participants with the specified reaction.
c. Mild: >2.0 to ≤5.0 cm; Moderate: >5.0 to ≤10.0 cm; Severe: >10.0 cm.
d. Mild: does not interfere with activity; Moderate: interferes with activity; Severe: prevents daily activity.
‡ Eight participants were between 16 and 17 years of age.
* Randomized participants in the safety analysis population who received at least 1 dose of the study intervention.

Frequency and Percentages of Participants with Solicited Systemic Reactions, by Maximum Severity, Within 7 Days After Each Dose – Participants 18 through 55 Years of Age‡ – Reactogenicity Subset of the Safety Population*

https://www.fda.gov/media/144413/download

	Pfizer-BioNTech COVID-19 Vaccine Dose 1 N[a]=2291 n[b] (%)	Placebo Dose 1 N[a] =2298 n[b] (%)	Pfizer-BioNTech COVID-19 Vaccine Dose 2 N[a] = 2098 n[b] (%)	Placebo Dose 2 N[a] = 2103 n[b] (%)
Fever				
≥38.0°C	85 (3.7)	20 (0.9)	331 (15.8)	10 (0.5)
≥38.0°C to 38.4°C	64 (2.8)	10 (0.4)	194 (9.2)	5 (0.2)
>38.4°C to 38.9°C	15 (0.7)	5 (0.2)	110 (5.2)	3 (0.1)
>38.9°C to 40.0°C	6 (0.3)	3 (0.1)	26 (1.2)	2 (0.1)
>40.0°C	0 (0.0)	2 (0.1)	1 (0.0)	0 (0.0)
Fatigue[c]				
Any	1085(47.4)	767 (33.4)	1247(59.4)	479 (22.8)
Mild	597 (26.1)	467 (20.3)	442 (21.1)	248 (11.8)
Moderate	455 (19.9)	289 (12.6)	708 (33.7)	217 (10.3)
Severe	33 (1.4)	11 (0.5)	97 (4.6)	14 (0.7)
Headache[c]				
Any	959 (41.9)	775 (33.7)	1085 (51.7)	506 (24.1)
Mild	628 (27.4)	505 (22.0)	538 (25.6)	321 (15.3)
Moderate	308 (13.4)	251 (10.9)	480 (22.9)	170 (8.1)
Severe	23 (1.0)	19 (0.8)	67 (3.2)	15 (0.7)
Chills[c]				
Any	321 (14.0)	146 (6.4)	737 (35.1)	79 (3.8)
Mild	230 (10.0)	111 (4.8)	359 (17.1)	65 (3.1)
Moderate	82 (3.6)	33 (1.4)	333 (15.9)	14 (0.7)
Severe	9 (0.4)	2 (0.1)	45 (2.1)	0 (0.0)

	Pfizer-BioNTech COVID-19 Vaccine Dose 1 N[a]=2291 n[b] (%)	Placebo Dose 1 N[a] =2298 n[b] (%)	Pfizer-BioNTech COVID-19 Vaccine Dose 2 N[a] = 2098 n[b] (%)	Placebo Dose 2 N[a] = 2103 n[b] (%)
Vomitting[d]				
Any	28 (1.2)	28 (1.2)	40 (1.9)	25 (1.2)
Mild	24 (1.0)	22 (1.0)	28 (1.3)	16 (0.8)
Moderate	4 (0.2)	5 (0.2)	8 (0.4)	9 (0.4)

Severe	0 (0.0)	1 (0.0)	4 (0.2)	0 (0.0)
Diarrhea[e]				
Any	255 (11.1)	270 (11.7)	219 (10.4)	177 (8.4)
Mild	206 (9.0)	217 (9.4)	179 (8.5)	144 (6.8)
Moderate	46 (2.0)	52 (2.3)	36 (1.7)	32 (1.5)
Severe	3 (0.1)	1 (0.0)	4 (0.2)	1 (0.0)
New or worsened muscle pain[c]				
Any	487 (21.3)	249 (10.8)	783 (37.3)	173 (8.2)
Mild	256 (11.2)	175 (7.6)	326 (15.5)	111 (5.3)
Moderate	218 (9.5)	72 (3.1)	410 (19.5)	59 (2.8)
Severe	13 (0.6)	2 (0.1)	47 (2.2)	3 (0.1)
New or worsened joint pain[c]				
Any	251 (11.0)	138 (6.0)	459 (21.9)	109 (5.2)
Mild	147 (6.4)	95 (4.1)	205 (9.8)	54 (2.6)
Moderate	99 (4.3)	43 (1.9)	234 (11.2)	51 (2.4)
Severe	5 (0.2)	0 (0.0)	20 (1.0)	4 (0.2)
Use of antipyretic or pain medication	638 (27.8)	332 (14.4)	945 (45.0)	266 (12.6)

Note: Events and use of antipyretic or pain medication were collected in the e-diary from Day 1 to Day 7 after each dose.
a. N = Number of participants reporting at least 1 yes or no response for the specified reaction after the specified dose.
b. n = Number of participants with the specified reaction.
c. Mild: does not interfere with activity; Moderate: interferes with activity; Severe: prevents daily activity.
d. Mild: 1 to 2 times in 24 hours; Moderate: >2 times in 24 hours; Severe: requires intravenous hydration
e. Mild: 2 to 3 loose stools in 24 hours; Moderate: 4 to 5 loose stools in 24 hours; Severe: 6 or more loose stools in 24 hours
f. Severity was not collected for use of antipyretic or pain medication
‡ Eight participants were between 16 and 17 years of age.
* Randomized participants in the safety analysis population who received at least 1 dose of the study intervention.

For the detailed data on the complete studies conducted on **Pfizer-BioNTech COVID-19 vaccine** on participants in other age groups as well, please see:
https://www.fda.gov/media/144413/download

The results from the clinical trials conducted for **Moderna COVID-19 vaccine** are presented next. The safety of Moderna COVID-19 Vaccine was evaluated in an ongoing Phase 3 randomized, placebo-controlled, observer-blind clinical trial conducted in the United States involving 30,351 participants 18 years of age and older who received at least one dose of Moderna COVID-19 Vaccine (n=15,185) or placebo (n=15,166).

Number Percentage of Participants With Solicited Local and Systemic Adverse Reactions Within 7 Days* After Each Dose in Participants 18-64 Years (Solicited Safety Set, Dose 1 and Dose 2)

https://www.fda.gov/media/144637/download

Local Adverse Reactions	Moderna COVID-19 Vaccine		Placebo[a]	
	Dose 1 (N=11,406) n (%)	Dose 2 (N=10,985) n (%)	Dose 1 (N=11,407) n (%)	Dose 2 (N=10,918) n (%)
Pain	9,908 (86.9)	9,873 (89.9)	2,177 (19.1)	2,040 (18.7)
Pain, Grade 3[b]	366 (3.2)	506 (4.6)	23 (0.2)	22 (0.2)
Axillary swelling/ tenderness	1,322 (11.6)	1,775 (16.2)	567 (5.0)	470 (4.3)
Axillary swelling/ tenderness, Grade 3[b]	37 (0.3)	46 (0.4)	13 (0.1)	11 (0.1)
Swelling (hardness) ≥25mm	767 (6.7)	1,389 (12.6)	34 (0.3)	36 (0.3)
Swelling (hardness), Grade 3[c]	62 (0.5)	182 (1.7)	3 (<0.1)	4 (<0.1)
Erythema (redness) ≥25mm	344 (3.0)	982 (8.9)	47 (0.4)	43 (0.4)
Erythema (redness), Grade 3[c]	34 (0.3)	210 (1.9)	11 (<0.1)	12 (0.1)

Systemic Adverse Reactions	Moderna COVID-19 Vaccine		Placebo[a]	
	Dose 1 (N=11,406) n (%)	Dose 2 (N=10,985) n (%)	Dose 1 (N=11,407) n (%)	Dose 2 (N=10,918) n (%)
Fatigue	4,384 (38.4)	7,430 (67.6)	3,282 (28.8)	2,687 (24.6)
Fatigue, Grade3[d]	120 (1.1)	1,174 (10.7)	83 (0.7)	86 (0.8)
Fatigue, Grade4[e]	1 (<0.1)	0 (0)	0 0)	0 (0)
Headache	4,030 (35.3)	6,898 (62.8)	3,304 (29.0)	2,760 (25.3)
Headache, Grade3[f]	219 (1.9)	553 (5.0)	162 (1.4)	129 (1.2)
Myalgia	2,699 (23.7)	6,769 (61.6)	1,628 (14.3)	1,411 (12.9)
Myalgia, Grade3[d]	73 (0.6)	1,113 (10.1)	38 (0.3)	42 (0.4)
Arthralgia	1,893 (16.6)	4,993 (45.5)	1,327 (11.6)	1,172 (10.7)
Arthralgia, Grade3[d]	47 (0.4)	647 (5.9)	29 (0.3)	37 (0.3)
Arthralgia, Grade4[e]	1 (<0.1)	0 (0)	0 (0)	0 (0)
Chills	1,051 (9.2)	5,341 (48.6)	730 (6.4)	658 (6.0)
Chills, Grade 3[g]	17 (0.1)	164 (1.5)	8 (<0.1)	15 (0.1)
Nausea/vomiting	1,068 (9.4)	2,348 (21.4)	908 (8.0)	801 (7.3)
Nausea/vomiting, Grade 3[h]	6 (<0.1)	10 (<0.1)	8 (<0.1)	8 (<0.1)
Fever	105 (0.9)	1,908 (17.4)	37 (0.3)	39 (0.4)
Fever, Grade3[i]	10 (<0.1)	184 (1.7)	1 (<0.1)	2 (<0.1)
Fever, Grade4[j]	4 (<0.1)	12 (0.1)	4 (<0.1)	2 (<0.1)
Use Of Antipyretic Or pain medication	2,656 (23.3)	6,292 (57.3)	1,523 (13.4)	1,248 (11.4)

* 7 days included day of vaccination and the subsequent 6 days. Events and use of antipyretic or pain medication were collected in the electronic diary (e-diary).
[a] Placebo was a saline solution.
[b] Grade 3 pain and axillary swelling/tenderness: Defined as any use of prescription pain reliever; prevents daily activity.
[c] Grade 3 swelling and erythema: Defined as >100mm / >10cm.
[d] Grade 3 fatigue, myalgia, arthralgia: Defined as significant; prevents daily activity.
[e] Grade 4 fatigue, arthralgia: Defined as requires emergency room visitor hospitalization.
[f] Grade 3 headache: Defined as significant; any use of prescription pain reliever or prevents daily activity.
[g] Grade 3 chills: Defined as prevents daily activity and requires medical intervention.
[h] Grade 3 nausea/vomiting: Defined as prevents daily activity, requires outpatient intravenous hydration.
[i] Grade 3 fever: Defined as ≥39.0°– ≤40.0°C / ≥102.1 – ≤104.0°F.

[j] Grade 4 fever: Defined as >40.0°C / >104.0°F.

Number Percentage of Participants With Solicited Local and Systemic Adverse Reactions Within 7 Days* After Each Dose in Participants 65 Years and Older (Solicited Safety Set, Dose 1 and Dose 2)

https://www.fda.gov/media/144637/download

Local Adverse Reactions	Moderna COVID-19 Vaccine		Placebo[a]	
	Dose 1 (N=3,762) n (%)	Dose 2 (N=3,692) n (%)	Dose 1 (N=3,748) n (%)	Dose 2 (N=3,648) n (%)
Pain	2,782 (74.0)	3,070 (83.2)	481 (12.8)	437 (12.0)
Pain, Grade 3[b]	50 (1.3)	98 (2.7)	32 (0.9)	18 (0.5)
Axillary swelling/ tenderness	231 (6.1)	315 (8.5)	155 (4.1)	97 (2.7)
Axillary swelling/ tenderness, Grade 3[b]	12 (0.3)	21 (0.6)	14 (0.4)	8 (0.2)
Swelling (hardness) ≥25mm	165 (4.4)	400 (10.8)	18 (0.5)	13 (0.4)
Swelling (hardness), Grade 3[c]	20 (0.5)	72 (2.0)	3 (<0.1)	7 (0.2)
Erythema (redness) ≥25mm	86 (2.3)	275 (7.5)	20 (0.5)	13 (0.4)
Erythema (redness), Grade 3[c]	8 (0.2)	77 (2.1)	2 (<0.1)	3 (<0.1)
Systemic Adverse Reactions	**Moderna COVID-19 Vaccine**		**Placebo[a]**	
	Dose 1 (N=3,762) n (%)	**Dose 2 (N=3,692) n (%)**	**Dose 1 (N=3,748) n (%)**	**Dose 2 (N=3,648) n (%)**
Fatigue	1,251 (33.3)	2,152 (58.3)	851 (22.7)	716 (19.6)
Fatigue, Grade3[d]	30 (0.8)	254 (6.9)	22 (0.6)	20 (0.5)
Headache	921 (24.5)	1,704 (46.2)	723 (19.3)	650 (17.8)
Headache, Grade3[e]	52 (1.4)	106 (2.9)	34 (0.9)	33 (0.9)
Myalgia	742 (19.7)	1,739 (47.1)	443 (11.8)	398 (10.9)
Myalgia, Grade3[d]	17 (0.5)	205 (5.6)	9 (0.2)	10 (0.3)
Arthralgia	618 (16.4)	1,291 (35.0)	456 (12.2)	397 (10.9)
Arthralgia, Grade3[d]	13 (0.3)	123 (3.3)	8 (0.2)	7 (0.2)
Chills	202 (5.4)	1,141 (30.9)	148 (4.0)	151 (4.1)
Chills, Grade 3[f]	7 (0.2)	27 (0.7)	6 (0.2)	2 (<0.1)
Nausea/vomiting	194 (5.2)	437 (11.8)	166 (4.4)	133 (3.6)
Nausea/vomiting, Grade 3[g]	4 (0.1)	10 (0.3)	4 (0.1)	3 (<0.1)
Nausea/vomiting, Grade 4[h]	0 (0)	1 (<0.1)	0 (0)	0 (0)
Fever	10 (0.3)	370 (10.0)	7 (0.2)	4 (0.1)
Fever, Grade3[i]	1 (<0.1)	18 (0.5)	1 (<0.1)	0 (0)
Fever, Grade4[j]	0 (0)	1 (<0.1)	2 (<0.1)	1 (<0.1)
Use Of Antipyretic Or pain medication	673 (17.9)	1,546 (41.9)	477 (12.7)	329 (9.0)

* 7 days included day of vaccination and the subsequent 6 days. Events and use of antipyretic or pain medication were collected in the electronic diary (e-diary).

[a] Placebo was a saline solution.

[b] Grade 3 pain and axillary swelling/tenderness: Defined as any use of prescription pain reliever; prevents daily activity.

[c] Grade 3 swelling and erythema: Defined as >100mm / >10cm.

[d] Grade 3 fatigue, myalgia, arthralgia: Defined as significant; prevents daily activity.

[e] Grade 3 headache: Defined as significant; any use of prescription pain reliever or prevents daily activity.

[f] Grade 3 chills: Defined as prevents daily activity and requires medical intervention.

[g] Grade 3 nausea/vomiting: Defined as prevents daily activity, requires outpatient intravenous hydration.

[h] Grade 4 nausea/vomiting: Defined as requires emergency room visit or hospitalization for hypotensive shock.

[i] Grade 3 fever: Defined as ≥39.0°– ≤40.0°C / ≥102.1 – ≤104.0°F.

[j] Grade 4 fever: Defined as >40.0°C / >104.0°F.

For the detailed data on the complete studies conducted on **Moderna COVID-19 vaccine** on participants in other age groups as well, please see:
https://www.fda.gov/media/144637/download

The results from the clinical trials conducted for Johnson & Johnson's **Janssen COVID-19 vaccine** are presented below. The safety of the Janssen COVID-19 vaccine has been assessed in Phase 3 Study which consists of 43,783 participants, of whom 21,895 adults aged 18 years and older received the vaccine. The complete data set about this study is available from:

Solicited Local Adverse Reactions Reported in the 7 Days Following Vaccination

https://www.fda.gov/media/146304/download

Adverse Reactions	Janssen COVID-19 Vaccine N=2,036 n (%) Individuals 18-59	Placebo N=2,049 n (%) Individuals 18-59	Janssen COVID-19 Vaccine N=1,320 n (%) Individuals 60+	Placebo N=1,331 n (%) Individuals 60+
Injection Site Pain				
Any	1,193(58.6)	357 (17.4)	439 (33.3)	207 (15.6)
Grade 3[a]	8 (0.4)	0	3 (0.2)	2 (0.2)
Injection Site Erythema				
Any (≥25 mm)	184 (9.0)	89 (4.3)	61 (4.6)	42 (3.2)
Grade 3[b]	6 (0.3)	2 (0.1)	1 (0.1)	0
Injection Site Swelling				
Any (≥25 mm)	142 (7.0)	32 (1.6)	36 (2.7)	21 (1.6)
Grade 3[b]	5 (0.2)	2 (0.1)	2 (0.2)	0

[a] Grade 3 injection site pain: Defined as incapacitating symptoms; inability to do work, school, or usual activities; use of narcotic pain reliever.

[b] Grade 3 injection site swelling and erythema: Defined as >100 mm.

Solicited Systemic Adverse Reactions Reported in the 7 Days Following Vaccination

https://www.fda.gov/media/146304/download

Adverse Reactions	Janssen COVID-19 Vaccine N=2,036 n (%) Individuals 18-59	Placebo N=2,049 n (%) Individuals 18-59	Janssen COVID-19 Vaccine N=1,320 n (%) Individuals 60+	Placebo N=1,331 n (%) Individuals 60+
Headache				
Any	905 (44.4)	508 (24.8)	401 (30.4)	294 (22.1)

Grade 3[a]	18 (0.9)	5 (0.2)	5 (0.4)	4 (0.3)
Fatigue				
Any	891 (43.8)	451 (22.0)	392 (29.7)	277 (20.8)
Grade 3[b]	25 (1.2)	4 (0.2)	10 (0.8)	5 (0.4)
Myalgia				
Any	796 (39.1)	248 (12.1)	317 (24.0)	182 (13.7)
Grade 3[b]	29 (1.4)	1 (<0.1)	3 (0.2)	5 (0.4)
Nausea				
Any	315 (15.5)	183 (8.9)	162 (12.3)	144 (10.8)
Grade 3[b]	3 (0.1)	3 (0.1)	3 (0.2)	3 (0.2)
Fever[c]				
Any	261 (12.8)	14 (0.7)	41 (3.1)	6 (0.5)
Grade 3[b]	7 (0.3)	0	1 (0.1)	0
Use of antipyretic or pain medication	538 (26.4)	123 (6.0)	130 (9.8)	68 (5.1)

[a] Grade 3 headache: Defined as incapacitating symptoms; requires bed rest and/or results in loss of work, school, or cancellation of social activities; use of narcotic pain reliever

[b] Grade 3 fatigue, myalgia, nausea: Defined as incapacitating symptoms; requires bed rest and/or results in loss of work, school, or cancellation of social activities; use of narcotic pain reliever.

[c] Fever of any grade: Defined as body temperature ≥38°C/100.4°F. Grade 3 fever: Defined as 39.0°C - 40.0°C (102.1°F - 104.0°F).

For the detailed data on the complete studies conducted on Johnson & Johnson's **Janssen COVID-19 vaccine** on participants in other age groups as well, please see: https://www.fda.gov/media/146304/download

Finally, for the detailed data on the complete studies conducted on **AstraZeneca COVID-19 vaccine** please see: https://www.thelancet.com/action/showPdf?pii=S0140-6736%2820%2932661-1

REFERENCES

1. https://www.fda.gov/media/144246/download
2. https://clinicaltrials.gov/ct2/show/NCT04505722
3. https://covid19.nih.gov
4. https://www.coronavirus.gov
5. https://clinicaltrials.gov/ct2/results?cond=COVID-19
6. https://www.wsj.com/articles/covid-19-vaccine-trial-volunteers-note-occasional-harsh-side-effects-11608114601
7. https://www.thelancet.com/action/showPdf?pii=S0140-6736%2820%2932661-1
8. https://www.thelancet.com/journals/lancet/article/PIIS0140-6736(20)32661-1/fulltext#sec1
9. https://www.thelancet.com/action/showPdf?pii=S0140-6736%2820%2932661-1
10. https://www.thelancet.com/cms/10.1016/S0140-6736(20)32661-1/attachment/4fb6f146-1b38-48e0-89cb-213bc4dca7ec/mmc1.pdf
11. https://www.thelancet.com/cms/10.1016/S0140-6736(20)32661-1/attachment/4fb6f146-1b38-48e0-89cb-213bc4dca7ec/mmc1.pdf
12. https://www.nejm.org/doi/full/10.1056/NEJMoa2034577
13. https://www.cdc.gov/coronavirus/2019-ncov/vaccines/different-vaccines/Pfizer-BioNTech.html
14. https://www.fda.gov/emergency-preparedness-and-response/coronavirus-disease-2019-covid-19/pfizer-biontech-covid-19-vaccine
15. https://www.fda.gov/media/144637/download
16. https://www.fda.gov/media/144413/download
17. https://www.fda.gov/media/146304/download
18. https://www.nature.com/articles/d41586-020-03165-9
19. https://www.worldometers.info/coronavirus/?utm_campaign=homeAdvegas1
20. https://www.beckershospitalreview.com/pharmacy/a-breakdown-of-the-4-covid-19-vaccine-trials-in-late-stage-testing.html
21. https://www.fiercepharma.com/pharma/despite-pfizer-s-high-efficacy-expectations-other-covid-vaccines-may-have-a-logistics-edge
22. https://www.AstraZeneca.com/media-centre/press-releases/2020/AstraZenecas-covid-19-vaccine-authorised-in-uk.html
23. https://www.pfizer.com/news/press-release/press-release-detail/pfizer -and-biontech-announce-publication-results-landmark
24. https://www.modernatx.com/cove-study
25. https://www.jnj.com/our-company/johnson-johnson-announces-its-first-phase-3-covid-19-vaccine-trial-ensemble-is-fully-enrolled
26. https://www.AstraZeneca.com/media-centre/press-releases/2020/azd1222hlr.html
27. https://www.cdc.gov/coronavirus/2019-ncov/vaccines/different-vaccines/how-they-work.html
28. https://www.nejm.org/doi/10.1056/NEJMoa2034201
29. https://www.thelancet.com/journals/lancet/article/PIIS0140-6736(20)32623-4/fulltext