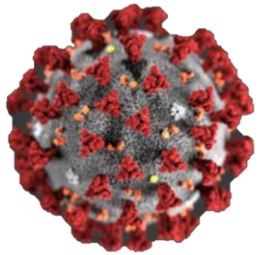

New Hampshire Coronavirus Disease 2019 Weekly Call for Healthcare Providers and Public Health Partners

February 25, 2021

Ben Chan
Elizabeth Talbot
Beth Daly
Lindsay Pierce

Thursday noon-time partner calls will focus on science, medical, and vaccine updates geared towards our healthcare partners

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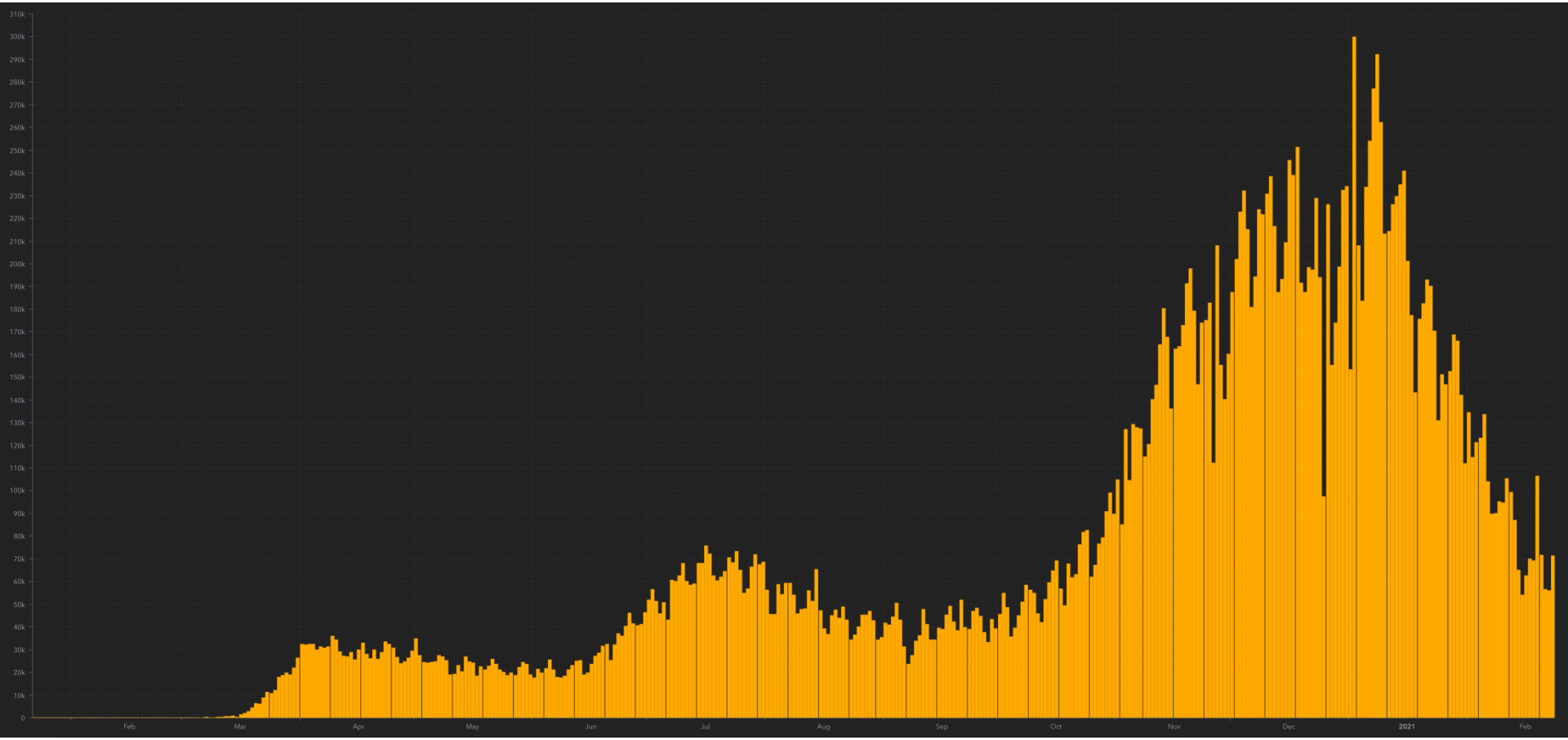
Department of Health and Human Services

Agenda

- Epidemiology Update
- FDA data summary: Janssen Biotech COVID-19 phase 3 clinical trial
- MMWR article: First month of COVID-19 vaccine safety monitoring – U.S., December 14, 2020 – January 13, 2021
- Questions & Answers (Q&A)

National Daily Incidence of COVID-19



- More than 28.3 million cumulative cases in the U.S. (25% of all global infections)
- More than 506,000 deaths in the U.S. from COVID-19 (20% of all global deaths)

JHU COVID-19 Dashboard

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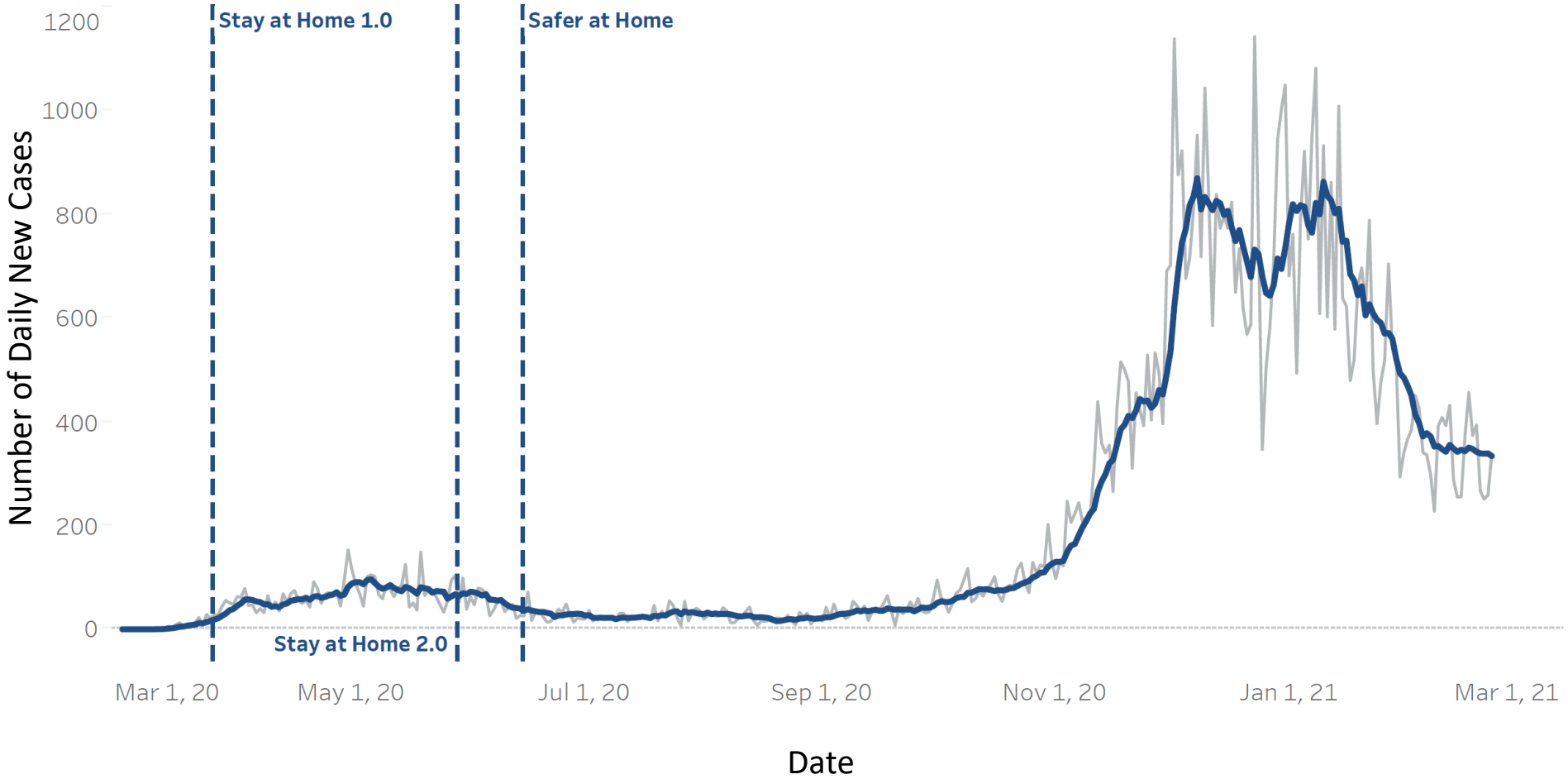
Number of New COVID-19 Cases per Day in NH



https://www.nh.gov/covid19/dashboard/overview.htm#dash

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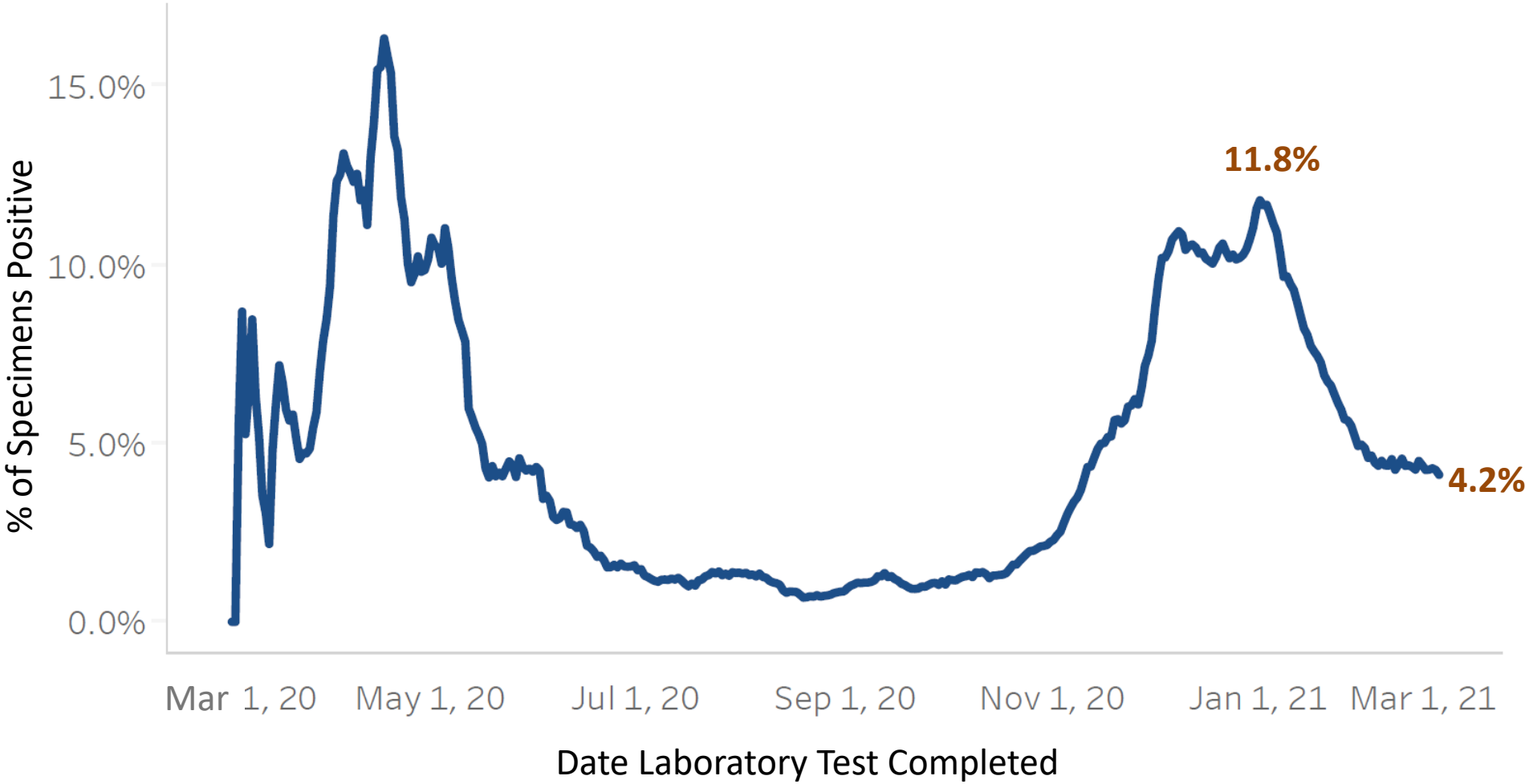
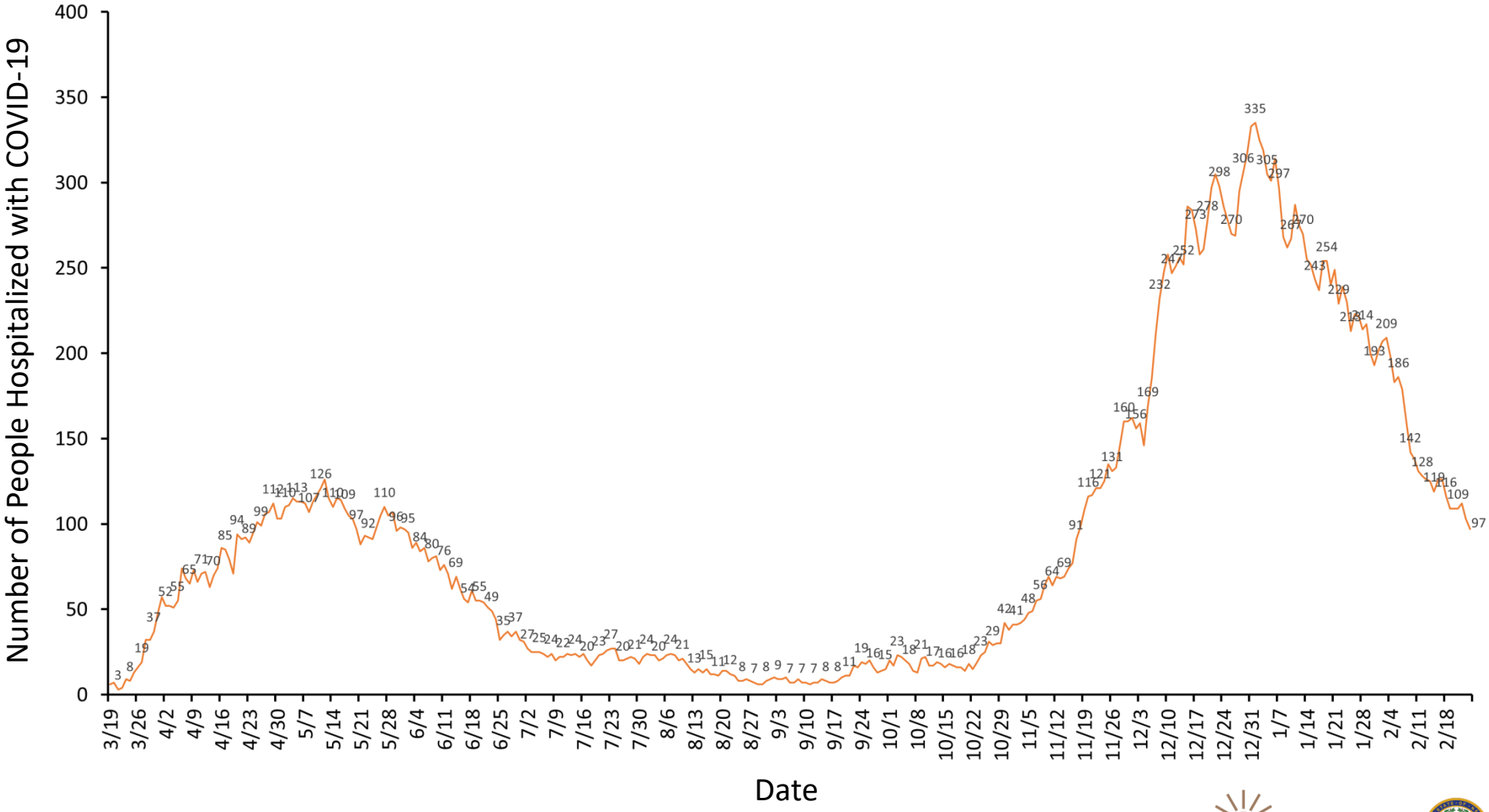
% of Tests (Antigen and PCR) Positive for COVID-19 (7-Day Average)



Number of People Hospitalized with COVID-19 Each Day in NH (Hospital Census)



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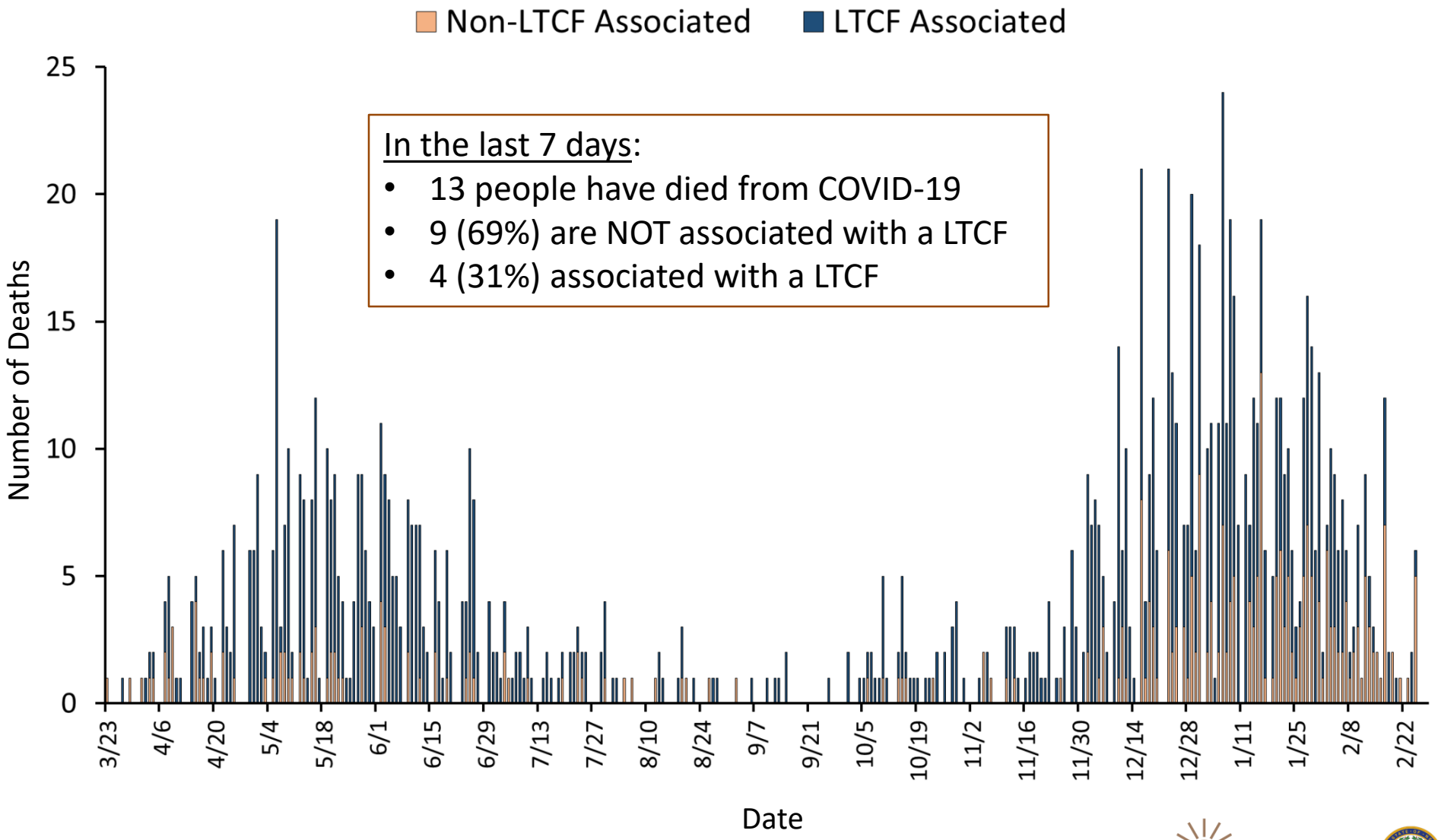
Number of COVID-19 Deaths in NH by Report Date



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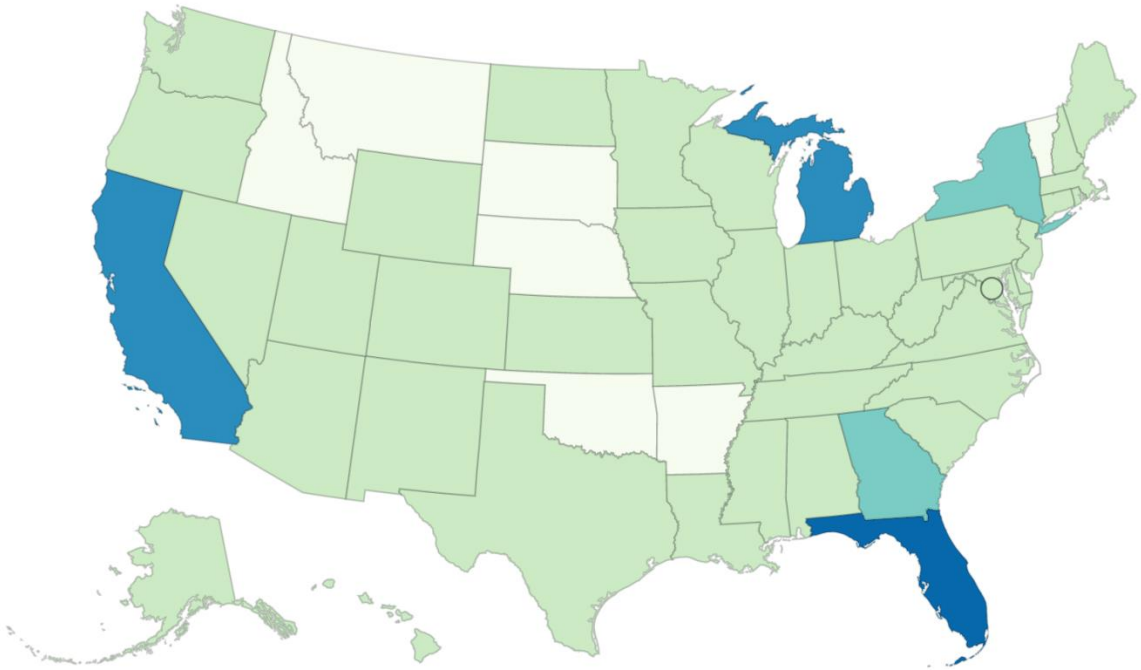
Variants of Concern (Current as of 2/23/21)

Variant	Reported Cases in US	Number of States Reporting
B.1.1.7	1881	45
B.1.351	46	14
P.1	5	4

https://www.cdc.gov/coronavirus/2019-ncov/transmission/variant-cases.html

Variant B.1.1.7



Number of Cases

- 0 to 0
- 1 to 100
- 101 to 200
- 201 to 300
- 401 to 500

Filters

Variant B.1.1.7

Territories AS GU MH FM MP PW PR VI

https://www.cdc.gov/coronavirus/2019-ncov/transmission/variant-cases.html

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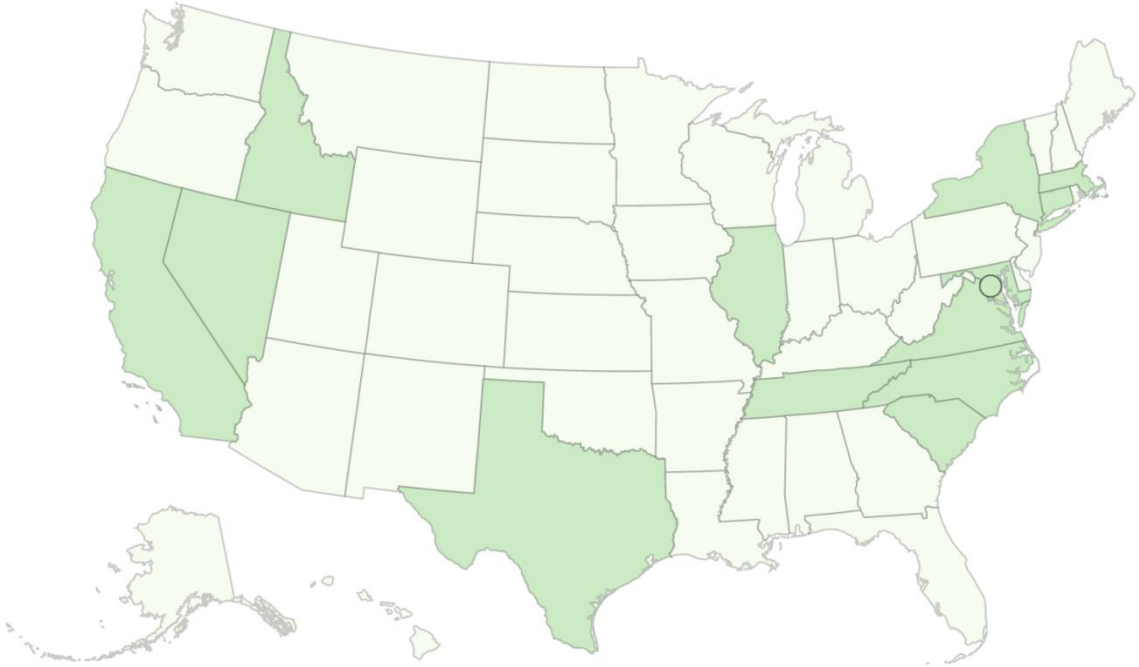
Variant B.1.351



Number of Cases

- 0 to 0
- 1 to 100
- 101 to 200
- 201 to 300
- 401 to 500

Filters

Variant B.1.351

Territories AS GU MH FM MP PW PR VI

https://www.cdc.gov/coronavirus/2019-ncov/transmission/variant-cases.html

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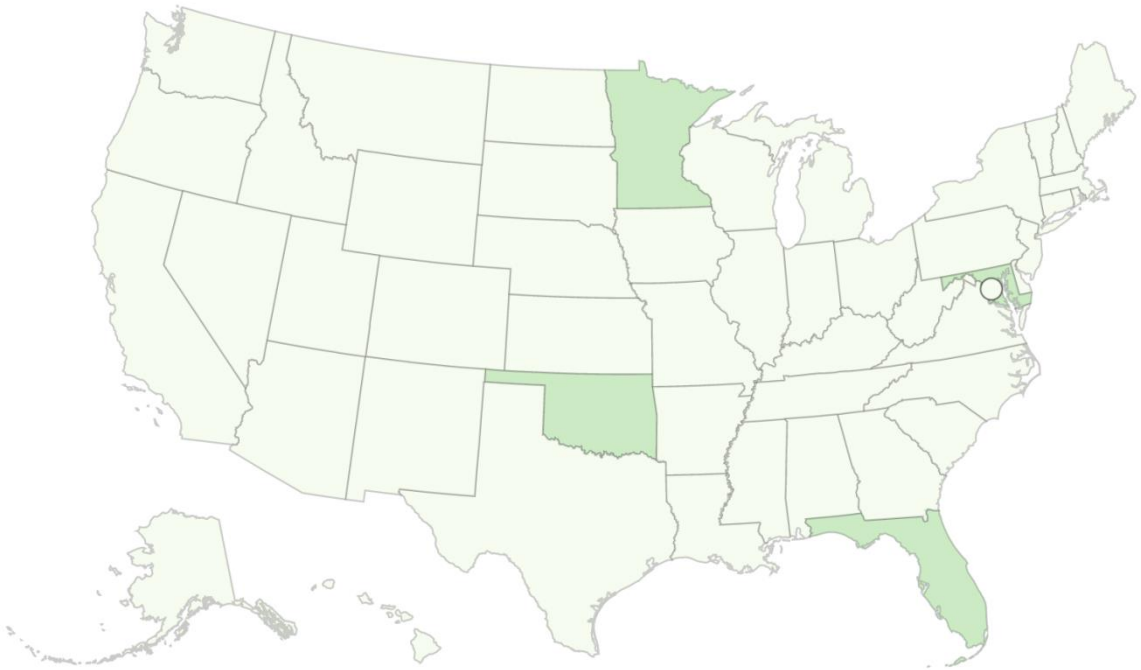
Variant P.1



Number of Cases

- 0 to 0
- 1 to 100
- 101 to 200
- 201 to 300
- 401 to 500

Filters

Variant P.1

Territories AS GU MH FM MP PW PR VI

https://www.cdc.gov/coronavirus/2019-ncov/transmission/variant-cases.html

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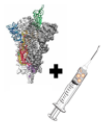
Janssen Biotech COVID-19 Vaccine

(A Pharmaceutical Company of Johnson & Johnson)

Selected COVID-19 Vaccines

Platform	Developer	Status
 **Nucleic Acid (mRNA)**	moderna	▪ 94% efficacy → EUA
	BIONTECH Pfizer	▪ 95% efficacy → EUA
 **Adenovirus Vector**	Janssen Pharmaceutical Companies of Johnson & Johnson	▪ Phase 3 results → likely Feb. 2021
	AstraZeneca	▪ Phase 3 results → likely Mar. 2021
 **Recombinant Protein and Adjuvant**	gsk SANOFI	▪ Phase 2 starts → Feb. 2021
	NOVAVAX Creating Tomorrow's Vaccines Today	▪ Phase 3 results → likely Mar. 2021

Borrowed from Dr. Fauci White House Press Briefing January 27, 2021

Janssen Biotech Ad26.COV2.S Vaccine

- Adenovirus type 26 (Ad26) vector: recombinant, replication-incompetent adenovirus vector carrying genetic instructions for our cells to produce the SARS-CoV-2 spike protein
- Same vaccine platform used in the Ebola vaccine and other investigational vaccines against Zika, HIV, malaria, RSV, HPV
- Supplied as a refrigerated suspension in multi-dose vials (5 doses/vial)
- Administered as a single intramuscular 0.5 mL injection
- Feb 4th: Request FDA Emergency Use Authorization (EUA)
- Feb 24th: FDA release of Phase 3 clinical trial data (~40,000 participants)
- Feb 26th: FDA's Vaccines and Related Biological Products Advisory Committee (VRBPAC) scheduled to meet to discuss EUA
- FDA could grant EUA possibly as soon as Saturday, Feb 27th
- ACIP scheduled to meet Sunday/Monday, Feb 28th – Mar 1st

https://www.nytimes.com/interactive/2020/science/coronavirus-vaccine-tracker.html

Vaccines and Related Biological Products Advisory Committee Meeting
February 26, 2021

FDA Briefing Document

Janssen Ad26.COV2.S Vaccine for the Prevention of COVID-19

Sponsor:
Janssen Biotech, Inc.

https://www.fda.gov/media/146217/download

Components in the Janssen Biotech Vaccine

- Replication-incompetent adenovirus vector carry the genetic instructions for our cells to make the SARS-CoV-2 spike protein
- Citric acid monohydrate
- Trisodium citrate dihydrate
- Ethanol
- 2-hydroxypropyl-β-cyclodextrin (HBCD)
- Polysorbate 80
- Sodium chloride
- Sodium hydroxide
- Hydrochloric acid

Phase 3 Clinical Trial Characteristics

- Studied in adults 18 years of age and older
- Studied as a single dose IM infection (also being studied in a parallel phase 3 study as a 2-dose series)
- Phase 3 clinical trials included ~40,000 participants
  - 47% of participants from the U.S.
  - 17% from Brazil
  - 13% from South Africa
  - 23% from 5 different countries in Latin America (Chile, Argentina, Colombia, Peru, Mexico)

https://www.fda.gov/media/146217/download

Primary Endpoint and Pre-specified Criteria

- Co-primary endpoints: Efficacy of a single dose of vaccine to prevent confirmed moderate to severe/critical COVID-19 occurring (1) at least 14 days after vaccination, and (2) at least 28 days after vaccination in study participants without evidence of prior SARS-CoV-2 infection at baseline (i.e., seronegative at time of vaccination)
- Other pre-specified study requirements:
  - At least 2 months of follow-up after vaccination in 50% of participants
  - At least 42 moderate to severe/critical cases of COVID-19 with onset at least 28 days after vaccination
  - At least 6 cases of COVID-19 among participants 60 years of age or older
  - At least 5 severe/critical cases of COVID-19 in the placebo group

https://www.fda.gov/media/146217/download

Secondary Endpoints

- Severe/critical COVID-19
- COVID-19 requiring medical intervention (i.e. hospitalization)
- COVID-19 related death
- Any symptomatic COVID-19
- Asymptomatic COVID-19 (inferred through evaluating seroconversion)

https://www.fda.gov/media/146217/download

Findings: Vaccine Efficacy

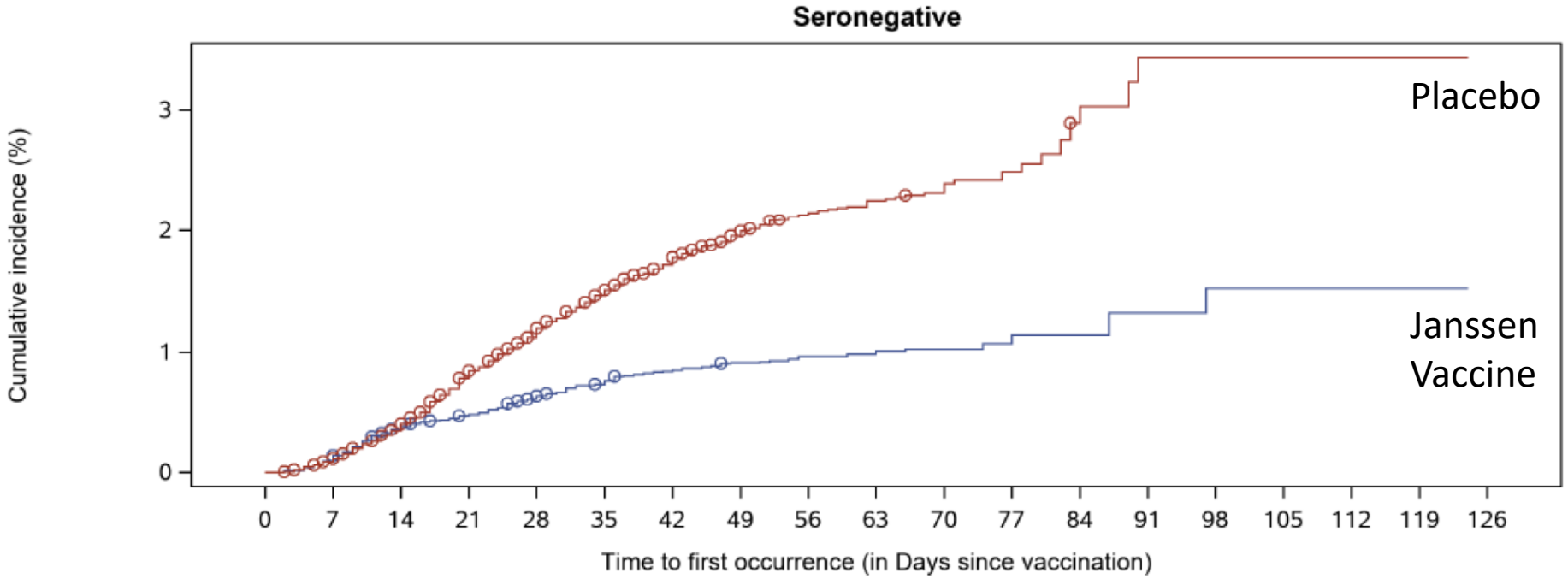
Primary Endpoint	Vaccine Efficacy
Lab-confirmed moderate to severe/critical COVID-19	66.9% (onset after 14 days) 66.1% (onset after 28 days)
Secondary Endpoints	**Vaccine Efficacy**
Lab-confirmed symptomatic COVID-19 of any severity (only 4 additional confirmed "mild" cases: 1 in vaccine group, 3 in placebo group)	66.9% (onset after 14 days) 66.5% (onset after 28 days)
Lab-confirmed severe/critical COVID-19	76.7% (onset after 14 days) 85.4% (onset after 28 days)
COVID-19 related hospitalizations*	93.1% (starting after 14 days) 100% (starting after 28 days)
COVID-19 related deaths (vaccine vs. placebo)	0 deaths vs. 7 deaths

* Vaccine efficacy based on small numbers; 2 people in the vaccine group and 29 people in the placebo group required hospitalization for COVID-19 starting 14 days after vaccination; 0 people in the vaccine group and 6 people in the placebo group required hospitalization for COVID-19 starting 28 days after vaccination.

https://www.fda.gov/media/146217/download

Cumulative Incidence Graph

Figure 1. Cumulative Incidence Curve of Centrally Confirmed Moderate to Severe/Critical COVID-19 Cases With Onset at Least 1 Day After Vaccination, Full Analysis Set



https://www.fda.gov/media/146217/download

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Findings: Subgroup Analysis

Subgroup Analyses	Vaccine Efficacy
18-59 years of age	63.7% (after 14 days) 66.1% (after 28 days)
60+ years of age	76.3% (after 14 days) 66.2% (after 28 days)
60+ years of age with comorbidity	64.9% (after 14 days) 42.3% (after 28 days)**

** 95% CI: -13.1% to 71.6%; observed trend of increasing VE with narrower confidence intervals as numbers of cases included in the analysis increased, indicating imprecise vaccine efficacy estimates related to small numbers.

Findings: Subgroup Analysis

Analysis by Geography	Vaccine Efficacy
United States	
Lab-confirmed moderate to severe/critical COVID-19	74.4% (onset after 14 days) 72.0% (onset after 28 days)
Lab-confirmed severe/critical COVID-19	78.0% (onset after 14 days) 85.9% (onset after 28 days)
South Africa (94.5% of specimens sequenced were B.1.351)	
Lab-confirmed moderate to severe/critical COVID-19	52.0% (onset after 14 days) 64.0% (onset after 28 days)
Lab-confirmed severe/critical COVID-19	73.1% (onset after 14 days) 81.7% (onset after 28 days)
Brazil (69.4% were P.2 lineage, no P.1 variant identified)	
Lab-confirmed moderate to severe/critical COVID-19	66.2% (onset after 14 days) 68.1% (onset after 28 days)
Lab-confirmed severe/critical COVID-19	81.9% (onset after 14 days) 87.6% (onset after 28 days)

https://www.fda.gov/media/146217/download

Assessing Asymptomatic Infection

- Asymptomatic infection: defined as a person without signs/symptoms of COVID-19 AND who tests positive by RT-PCR or develops a positive serology (non-spike antibody testing occurred Day 1, Day 29, and Day 71)
- Asymptomatic infection endpoints being studied:
  - Vaccine efficacy against all SARS-CoV-2 infection (including asymptomatic infection) will be analyzed when 15,000 participants with Day 71 serology are available
  - Vaccine efficacy against "asymptomatic or undetected infection" with onset 28+ days post-vaccination will be analyzed when all participants have at least 6 months of follow-up
- Preliminary analysis of Day 71 serology results from 2,650 participants: 10 people in vaccine group seroconverted without previous symptoms vs. 37 in placebo group (estimated vaccine efficacy of 74%)
  - FDA: "There is uncertainty about the interpretation of these data and definitive conclusions cannot be drawn at this time"
  - The role of vaccine in preventing asymptomatic transmission is still unclear

https://www.fda.gov/media/146217/download

Common Vaccine Side Effects

- 50% of vaccine recipients reported any local side effects
- 55% of vaccine recipients reported any systemic side effects
- Most common local side effects:
  - Pain (48.6%),
  - Redness (7.3%)
  - Swelling (5.3%)
- Most common systemic side effects:
  - Headache (38.9%)
  - Fatigue (38.2%)
  - Muscle pain (33.2%)
  - Nausea (14.2%)
  - Fever (9.0%)

https://www.fda.gov/media/146217/download

Adverse Events Being Monitored

- Thromboembolic events: 15 events in the vaccine group, 10 events in the placebo group
- Tinnitus (ringing in the ears): 6 reports in vaccine group, 0 reports in the placebo group
- Numbers of thromboembolic events and tinnitus are very small, and it is unclear if the vaccine contributed/caused – will be monitored with vaccine rollout
- No differences in Bell's Palsy between groups (2 cases in vaccine group, 2 cases in the placebo group)
- No reports of anaphylaxis, but a higher number of "angioedema" events in vaccine vs. placebo group (44 vs. 28), and a greater number of urticaria events in vaccine vs. placebo group within 7 days of vaccination (5 vs. 1)

https://www.fda.gov/media/146217/download

MMWR Article: First Month of COVID-19 Vaccine Safety Monitoring

https://www.cdc.gov/mmwr/volumes/70/wr/pdfs/mm7008e3-H.pdf

Reporting vaccine adverse events

- Providers are required by the FDA to report the following adverse events that occur following COVID-19 vaccination to VAERS:
  - Vaccine administration errors
  - Serious adverse events
  - Cases of Multisystem Inflammatory Syndrome (MIS)
  - Cases of COVID-19 that result in hospitalization or death
- Reporting is required even if the vaccine is not directly connected or causal
- Reporting is also encouraged for other clinical significant adverse events
- V-safe: voluntary smartphone-based tool that uses text messages and web surveys to perform check-ins after vaccination

https://www.cdc.gov/vaccines/covid-19/info-by-product/clinical-considerations.html#Reporting-adverse-events

Centers for Disease Control and Prevention
MMWR
Morbidity and Mortality Weekly Report
Early Release / Vol. 70
February 19, 2021

First Month of COVID-19 Vaccine Safety Monitoring — United States, December 14, 2020–January 13, 2021

- Descriptive analysis of safety data from the first month of vaccination
- 13,794,904 vaccine doses were administered during time frame
  - Pfizer-BioNTech vaccine: includes 1st and 2nd doses
  - Moderna vaccine: includes only 1st dose
- Evaluated VAERS and v-safe data

https://www.cdc.gov/mmwr/volumes/70/wr/pdfs/mm7008e3-H.pdf

VAERS: Serious adverse events and deaths

- 6,994 reports of COVID-19 associated adverse events:
  - 6,354 (91%) were classified as non-serious
  - 640 (9%) were classified as serious, including 113 deaths (two-thirds of deaths occurred among LTCF residents)
- Investigations into cause of deaths (death certificates, autopsy, etc.) were consistent with background all-cause mortality – no unexpected patterns identified that suggest a causal relationship with vaccination
- 78 (65%) reports of death were in LTCF residents after vaccination: about one-half were in residents on hospice or who had a DNR
  - CDC estimates that among the 1 million LTCF residents vaccinated in the first month, ~7,000 coincidental, temporally associated deaths from all causes would be expected – deaths in LTCF residents are consistent with expected all-cause mortality

https://www.cdc.gov/mmwr/volumes/70/wr/pdfs/mm7008e3-H.pdf

VAERS: Anaphylaxis

- 62 reports of anaphylaxis confirmed
  - 46 (74%) after receipt of Pfizer-BioNTech vaccine
  - 16 (26%) after receipt of Moderna vaccine
- Rate of anaphylaxis after receipt of COVID-19 vaccine: 4.5 cases per million doses administered
  - Inactivated influenza vaccine: 1.4 cases per million doses
  - Pneumococcal polysaccharide vaccine: 2.5 cases per million doses
  - Herpes zoster vaccine: 9.6 cases per million doses
- Occurrence of anaphylaxis after receipt of COVID-19 vaccines is within the range reported with other vaccines

https://www.cdc.gov/mmwr/volumes/70/wr/pdfs/mm7008e3-H.pdf

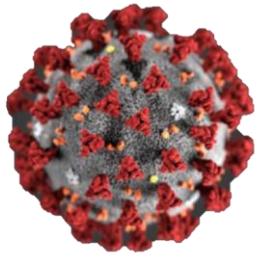
V-Safe: Common Vaccine Side Effects

TABLE 2. Percentage of v-safe enrollees who completed at least one survey (N = 1,602,065) with local and systemic reactions reported for day 0–7 and for day 1 after receiving Pfizer-BioNTech and Moderna COVID-19 vaccines — v-safe,* United States, December 14, 2020–January 13, 2021

	Percentage of v-safe enrollees reporting reactions			
	Both vaccines	Pfizer-BioNTech vaccine		Moderna vaccine
Local and systemic reaction	Day 0–7	Dose 1, day 1	Dose 2, day 1	Dose 1, day 1
Injection site pain	70.9	72.9	79.3	78.1
Fatigue	33.5	21.9	53.5	25.1
Headache	29.5	17.5	43.4	19.9
Myalgia	22.9	14.7	47.2	18.3
Chills	11.6	5.5	30.6	8.4
Fever	11.4	5.8	29.2	8.2
Injection site swelling	10.8	6.2	8.6	12.6
Joint pain	10.4	5.3	23.5	7.3
Nausea	8.9	4.2	14.0	5.5

- Findings are similar to patterns seen in vaccine clinical trials
- Higher frequency of side effects after the second dose
- Side effects should not dissuade people from the second dose
  - Symptoms usually occur within 1-2 days after vaccination and resolve within 1-3 days

https://www.cdc.gov/mmwr/volumes/70/wr/pdfs/mm7008e3-H.pdf



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