



COVID-19

NDA Vaccination Information Session

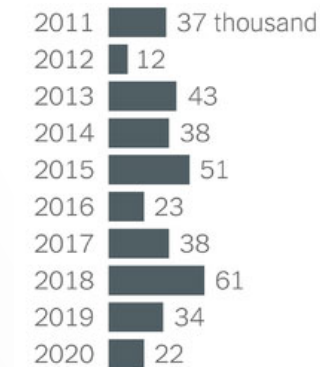
GOALS:

- Discuss COVID-19 disease
- Discuss COVID-19 in teens
- Discuss the mRNA vaccine now available for teens 12-15 years
- Discuss benefits, risks, contraindications and precautions with COVID-19 vaccination

COVID-19 BY THE NUMBERS

[HTTPS://CORONAVIRUS.JHU.EDU/](https://coronavirus.jhu.edu/)

- Global Confirmed **166,827,347**
- Global Deaths **3,456,630**
- U.S. Confirmed **33,111,163**
- U.S. Deaths **589,829**



Flu deaths in the United States
compared with Covid deaths

Covid **501**

Note: Covid figure is for the past year as of Feb. 23, 2021.

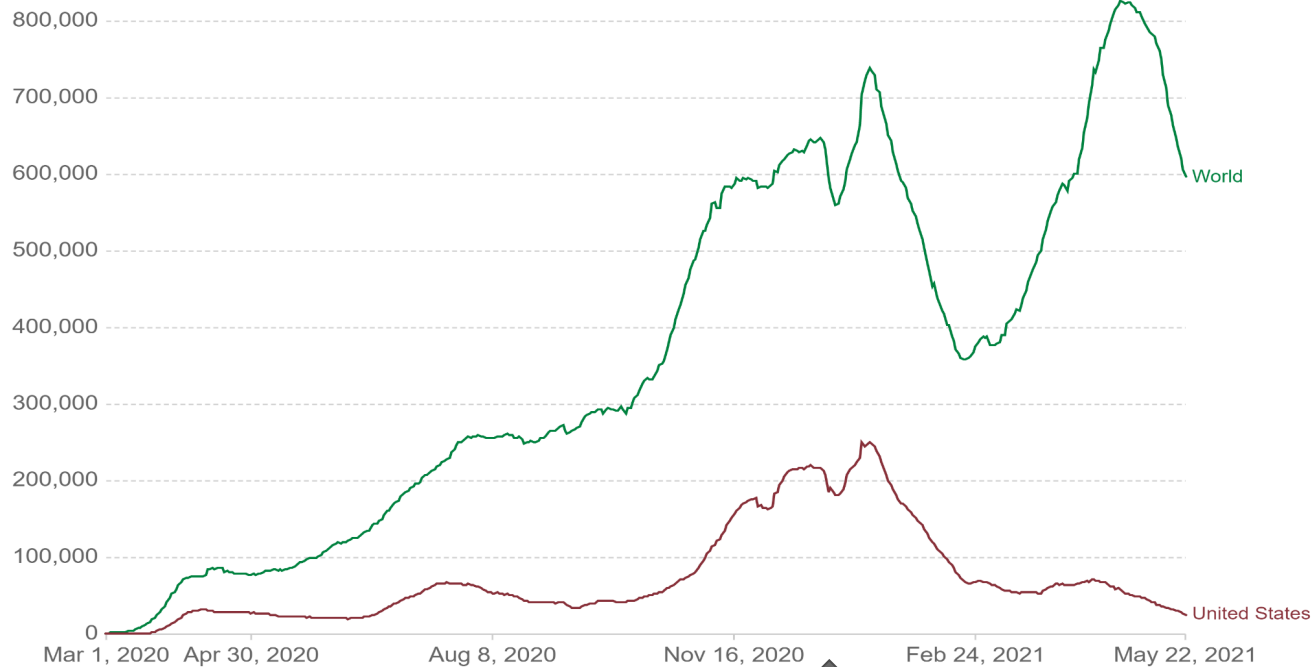
MAY 26: Almost 1.5 billion doses of vaccine given worldwide

COVID-19 CASES OVER TIME – US AND GLOBAL (ARROW IS COVID-19 VACCINE FIRST DOSE USA)

Daily new confirmed COVID-19 cases

Shown is the rolling 7-day average. The number of confirmed cases is lower than the number of actual cases; the main reason for that is limited testing.

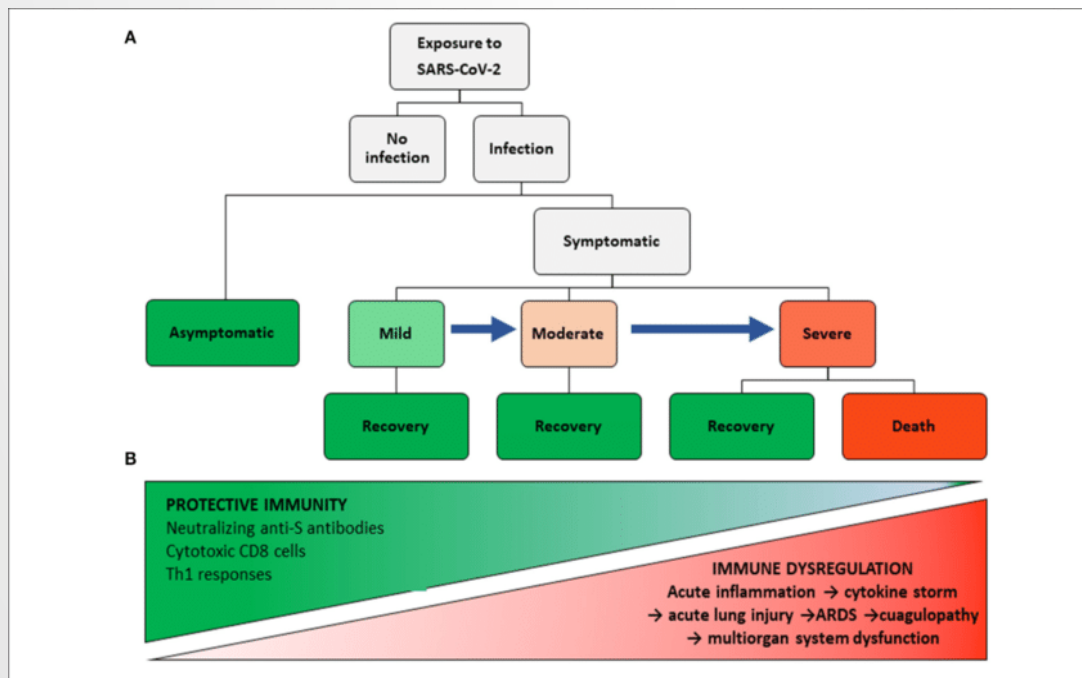
Our World
in Data



Source: Johns Hopkins University CSSE COVID-19 Data

CC BY

SPECTRUM OF COVID-19 ILLNESS



“Long COVID” (one month later: continued fatigue, brain “fog”, loss of taste/smell, difficulty breathing, chest pain)

“Post-intensive care syndrome”

...indirect/not yet determined effects (still learning)

COVID-19 INFECTION IN KIDS IN US IS *USUALLY MILD*_(AAP.ORG/CDC.GOV)

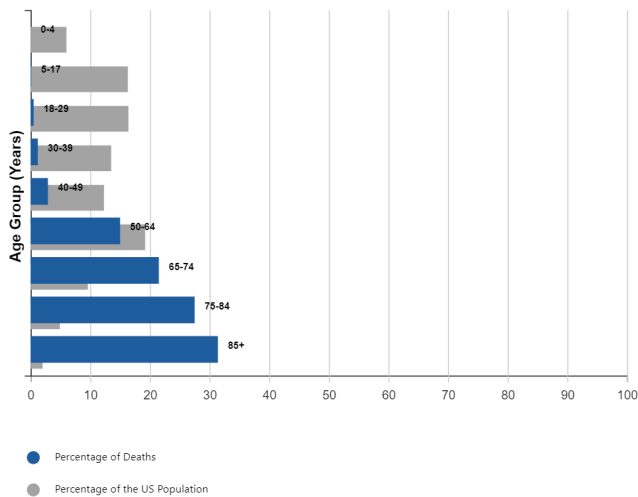
- 3.9 M children have tested positive as of May 13
- 13,000 adolescents have been hospitalized
- **Very few** cases of child/teen COVID-19 resulted in **death** (0—0.03%) (**397** in US May 2021 under 18 years)
- Multi-System Inflammatory Syndrome of Children is a more severe complication (MIS-C)
 - Severe **hyperinflammatory syndrome** occurring 2-6 weeks after acute SARS-CoV-2 infection, resulting in a wide range of manifestations and complications (multiple body systems). Cardiac complications common.
 - 60-70% of patients are admitted to intensive care, 1-2% die_{1,2}
 - 3,742 MIS-C cases have been reported to national surveillance as of May 3, 2021 – Median age of 9, with 21% (804) of cases occurred in adolescents 12-17 years

COVID-19 DEATHS IN UNITED STATES

MAY 22, 2021 CDC.GOV

Deaths by Age Group:

Data from 466,699 deaths. Age group was available for 466,662 (99%) deaths.



☒ Show Percentage of the US Population that is in this demographic category

Deaths by Age Group

Date generated: Sun May 23 2021 14:57:40 GMT-0400 (Eastern Daylight Time)

Age Group	Percentage of deaths	Count of deaths	Percent of US population
0-4 Years	<0.1	121	6
5-17 Years	0.1	276	16.3
18-29 Years	0.5	2339	16.4
30-39 Years	1.2	5496	13.5
40-49 Years	2.9	13617	12.3
50-64 Years	15	69899	19.2
65-74 Years	21.5	100358	9.6
75-84 Years	27.5	128217	4.9
85+ Years	31.4	146339	2

SUMMARY OF THE AVAILABLE EVIDENCE: ADOLESCENTS 12–17 YEARS OF AGE ARE AT RISK OF SEVERE ILLNESS FROM COVID-19

- ▪ Over 1.5 million reported cases and >13,000 hospitalizations to date – Hospitalization rate higher than 2009-10 H1N1 pandemic
- ▪ Clinical presentation of MIS-C more severe in adolescents than in younger children COVID-19 in adolescents may also indirectly impact others' health
- ▪ Adolescents contribute to transmission in households and communities – Including older adults at higher risk of COVID-19
- ▪ Adolescents represent an increasing proportion of recent COVID-19 cases

THE INDIRECT EFFECTS OF COVID-19 ON KIDS IN US:

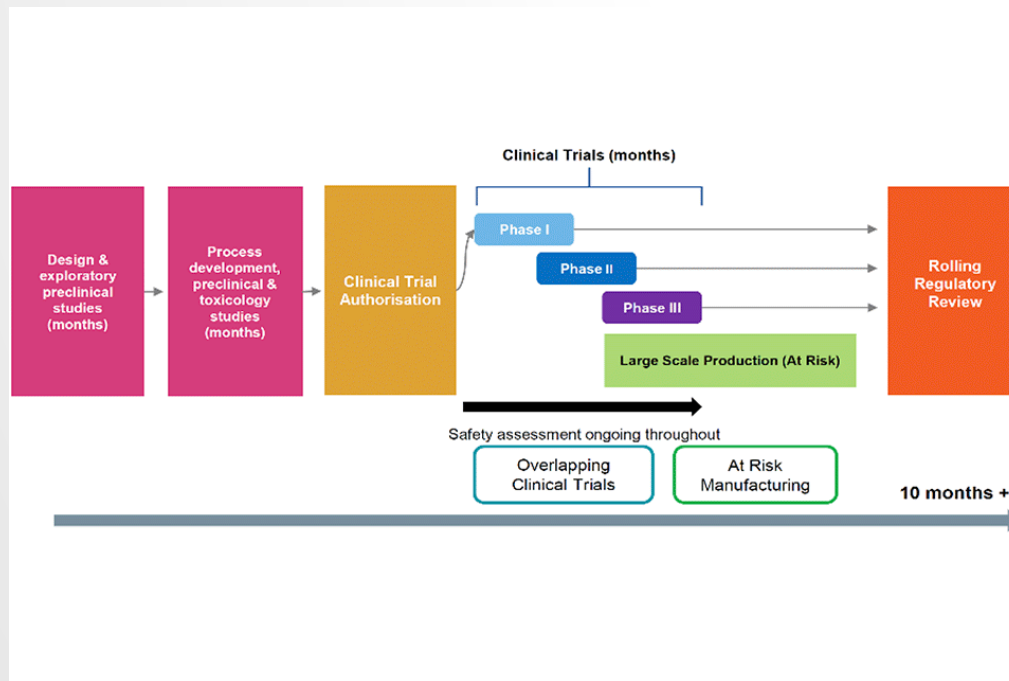


Childrenshospitals.org 4/28/21

1. Family stress – 4/10 adults reporting stress, higher if kids under 18 in house
2. Developmental issues (inc mental health)
3. Widening educational gap
4. Adverse childhood experiences
5. Rare related illness (MIS-C) – 3K hosp, 36 deaths
6. Fewer wellness visits (44% fewer outpatient mental health visits, 75% reduction in dental)
7. Lingering physical challenges – long term health effects

NOTE: **GLOBAL EFFECTS** ON CHILDREN MORE SEVERE (hunger, educational effects, disruption of healthcare)

VACCINE DEVELOPMENT PROCESS



VACCINES AVAILABLE IN US

Vast majority of 250 M vaccines administered in US are mRNA

Pfizer - mRNA

*mRNA vaccine 12+

***Dec 11, 2020** EUA 16 and older

37,586 participants 16+ monitored at least 2 months

95% effective 2 weeks after 2nd dose (8 cases in vaccine group 162 in placebo)

***May 10, 2021** EUA 12-15 years

*Reported on additional 2260 participants with non-inferior antibody response and 100% effectiveness

*Side effect profile same as 16 and older

Moderna - mRNA

*mRNA vaccine for 18+ (just submitted for 12-17 this week)

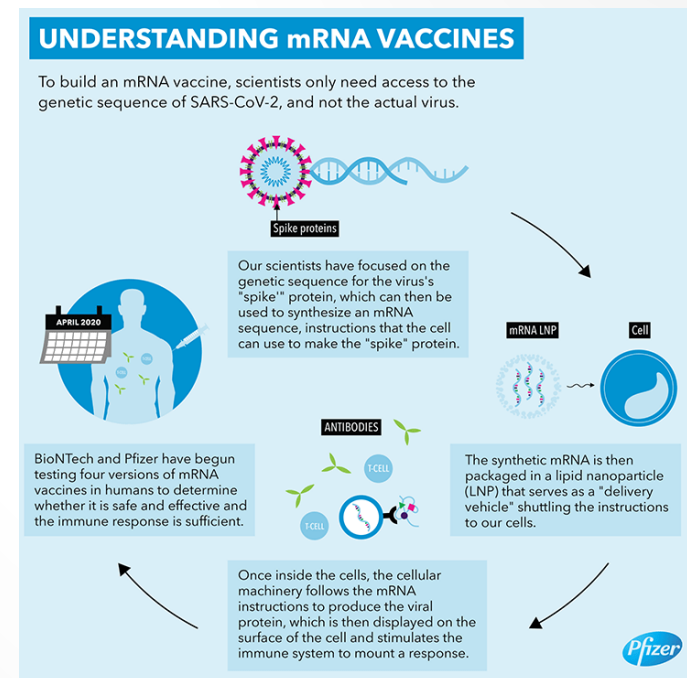
*94.1% effective 2 weeks after second dose

Johnson and Johnson

*Adenoviral vector vaccine for 18+ years

*Single dose, 8.5 Million doses given

*Rare side effect in women 18-49 TTS (thrombosis with thrombocytopenia syndrome) 7 per 1 M



MRMA VACCINE BASICS

- Pfizer vaccine is the only one approved for 12-15 years. Moderna submitted approval expected in June.
- Parental consent is required if under age 18 years
- Pfizer is a 2 dose series given 3 weeks apart
- Local pediatric offices, pharmacies and Cincinnati Childrens have online appointments (www.healthcollab.org)
- The vaccines are free (no co-pay)
- Vaccines can be given with other vaccines needed

SAFETY

- Common side effects: site reactions (swelling, redness, soreness), fever, headache, chills, muscle aches
- V-Safe monitoring system
- Two serious side effects identified through VAERS – Anaphylaxis (very rare – 2-4/million doses in Pfizer/Moderna) and TTS (7 cases per million doses of J&J vaccine in women 18-49)
- Recent reports of myocarditis are not above baseline

MEDICAL PROFESSIONAL ORGANIZATIONS STATEMENTS ON VACCINES

- American Academy of Pediatrics 5/12/21 – All teens 12 and up and caregivers should consider COVID-19 vaccination (<https://pediatrics.aappublications.org/content/early/2021/05/11/peds.2021-050531#T1>)
- American College of Obstetricians and Gynecologists – 4/28/21 (<https://www.acog.org/clinical/clinical-guidance/practice-advisory/articles/2020/12/vaccinating-pregnant-and-lactating-patients-against-covid-19>)
 - Pregnant women should be offered vaccine
 - Lactating women should be offered vaccine
 - There is no evidence of the vaccine causing problems with fertility
 - There is evidence that symptomatic pregnant patients with COVID-19 are at increased risk of more severe illness compared to nonpregnant peers (increased risk of ICU admission, need for ventilatory support in death).

REASONS TO CONSIDER VACCINATION FOR TEENS 12-15 YEARS

1. FOR HERSELF

- *RISK OF COVID-19 INFECTION IS LOW...BUT *NOT* ZERO
- *VACCINE IS SAFE AND EFFECTIVE
- *RETURN TO NORMAL ACTIVITIES
- *NO NEED TO QUARANTINE or TEST AFTER EXPOSURE IF VACCINATED and ASYMPTOMATIC

2. FOR FRIENDS AND FAMILY

- *HELP PROTECT OTHERS BY NOT SPREADING MILD ILLNESS
- *REDUCE THE INDIRECT EFFECTS OF COVID-19 IN HOUSEHOLD

3. FOR COMMUNITY

- *COMMUNITY IMMUNITY WILL DECREASE VARIANTS
- *RETURN TO NORMAL
- *REDUCE THE INDIRECT AND NOT FULLY MEASURED EFFECTS OF COVID-19 ON OUR WORLD

PFIZER VACCINE AND FERTILITY

- Here are some additional truths about COVID-19 vaccines and pregnancy (www.cincinnatichildrens.org):
- During the COVID-19 vaccine clinical trials, participants were asked to not get pregnant. Despite this request, 23 women became pregnant after receiving the Pfizer-BioNTech vaccine as part of the clinical trials.
- No adverse effects were reported by those women.
- Pfizer recently launched a separate clinical trial involving healthy pregnant women to continue to gather evidence on safety and efficacy.
- Also, the Centers for Disease Control and Prevention (CDC) has developed a site to collect information on COVID-related side effects. About 30,000 pregnant women have enrolled in that CDC registry as of Jan. 27, 2021.
- In the enrolled population, the registry shows no difference in miscarriage, stillbirth, pregnancy complications, or neonatal outcomes between background rates and pregnant vaccinated individuals. (next slide)
- Vaccine safety data will continue to be collected for pregnant women, and follow-up is planned for the first year of infant life.

NEW ENGLAND JOURNAL OF MEDICINE

APRIL 21, 2021

Table 4. Pregnancy Loss and Neonatal Outcomes in Published Studies and V-safe Pregnancy Registry Participants.

Participant-Reported Outcome	Published Incidence [*]	V-safe Pregnancy Registry [†]
	%	no./total no. (%)
Pregnancy loss among participants with a completed pregnancy		
Spontaneous abortion: <20 wk ^{15,17}	10–26	104/827 (12.6) [‡]
Stillbirth: ≥ 20 wk ^{18,20}	<1	1/725 (0.1) [§]
Neonatal outcome among live-born infants		
Preterm birth: <37 wk ^{21,22}	8–15	60/636 (9.4) [¶]
Small size for gestational age ^{23,24}	3.5	23/724 (3.2)
Congenital anomalies ^{25,26*}	3	16/724 (2.2)
Neonatal death ^{26††}	<1	0/724

* The populations from which these rates are derived are not matched to the current study population for age, race and ethnic group, or other demographic and clinical factors.

† Data on pregnancy loss are based on 827 participants in the v-safe pregnancy registry who received an mRNA Covid-19 vaccine (BNT162b2 [Pfizer–BioNTech] or mRNA-1273 [Moderna]) from December 14, 2020, to February 28, 2021, and who reported a completed pregnancy. A total of 700 participants (84.6%) received their first eligible dose in the third trimester. Data on neonatal outcomes are based on 724 live-born infants, including 12 sets of multiples.

‡ A total of 96 of 104 spontaneous abortions (92.3%) occurred before 13 weeks of gestation.

§ The denominator includes live-born infants and stillbirths.

¶ The denominator includes only participants vaccinated before 37 weeks of gestation.

|| Small size for gestational age indicates a birthweight below the 10th percentile for gestational age and infant sex according to INTERGROWTH-21st growth standards (<http://intergrowth21.ndog.ox.ac.uk>). These standards draw from an international sample including both low-income and high-income countries but exclude children with coexisting conditions and malnutrition. They can be used as a standard for healthy children growing under optimal conditions.

** Values include only major congenital anomalies in accordance with the Metropolitan Atlanta Congenital Defects Program 6-Digit Code Defect List (www.cdc.gov/ncbddd/birthdefects/macdp.html); all pregnancies with major congenital anomalies were exposed to Covid-19 vaccines only in the third trimester of pregnancy (i.e., well after the period of organogenesis).

†† Neonatal death indicates death within the first 28 days after delivery.

CONTRAINDICATIONS AND PRECAUTIONS TO COVID-19 VACCINE

- **CONTRAINDICATIONS:**

- Severe allergic reaction (e.g., anaphylaxis) after a previous dose or to a component of an mRNA COVID-19 vaccine (Moderna or Pfizer-BioNTech)
- Immediate allergic reaction[†] of any severity to a previous dose or known (diagnosed) allergy to a component of the vaccine
- **Note:** Persons who have a contraindication to an mRNA COVID-19 vaccine (Moderna or Pfizer-BioNTech) may be able to receive the Janssen COVID-19 vaccine (see footnote).[±]

- **PRECAUTIONS:**

- History of an immediate allergic reaction[†] to any other vaccine or injectable therapy (i.e., intramuscular, intravenous, or subcutaneous vaccines or therapies)
 - This includes people with a reaction to a vaccine or injectable therapy that contains multiple components, one of which is a vaccine component, but for whom it is unknown which component elicited the immediate allergic reaction.
- People with a contraindication to Janssen COVID-19 vaccine have a precaution to both mRNA vaccines (see footnote).[±]
- Moderate to severe acute illness

FOR MORE INFORMATION:

- Contact your pediatrician or family physician office
- www.cincinnatichildrens.org
- www.aap.org
- www.healthcollab.org
- www.nkyhealth.org