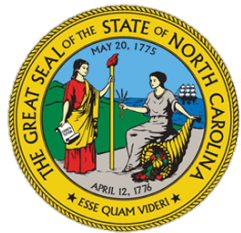


NCDHHS COVID-19 Vaccine Pediatric Readiness Discussion

February 18, 2022



NC DEPARTMENT OF
**HEALTH AND
HUMAN SERVICES**



FDA DELAYS AUTHORIZATION FOR THE PFIZER 6 MONTHS – 4 YEARS VACCINE

Authorization Update:



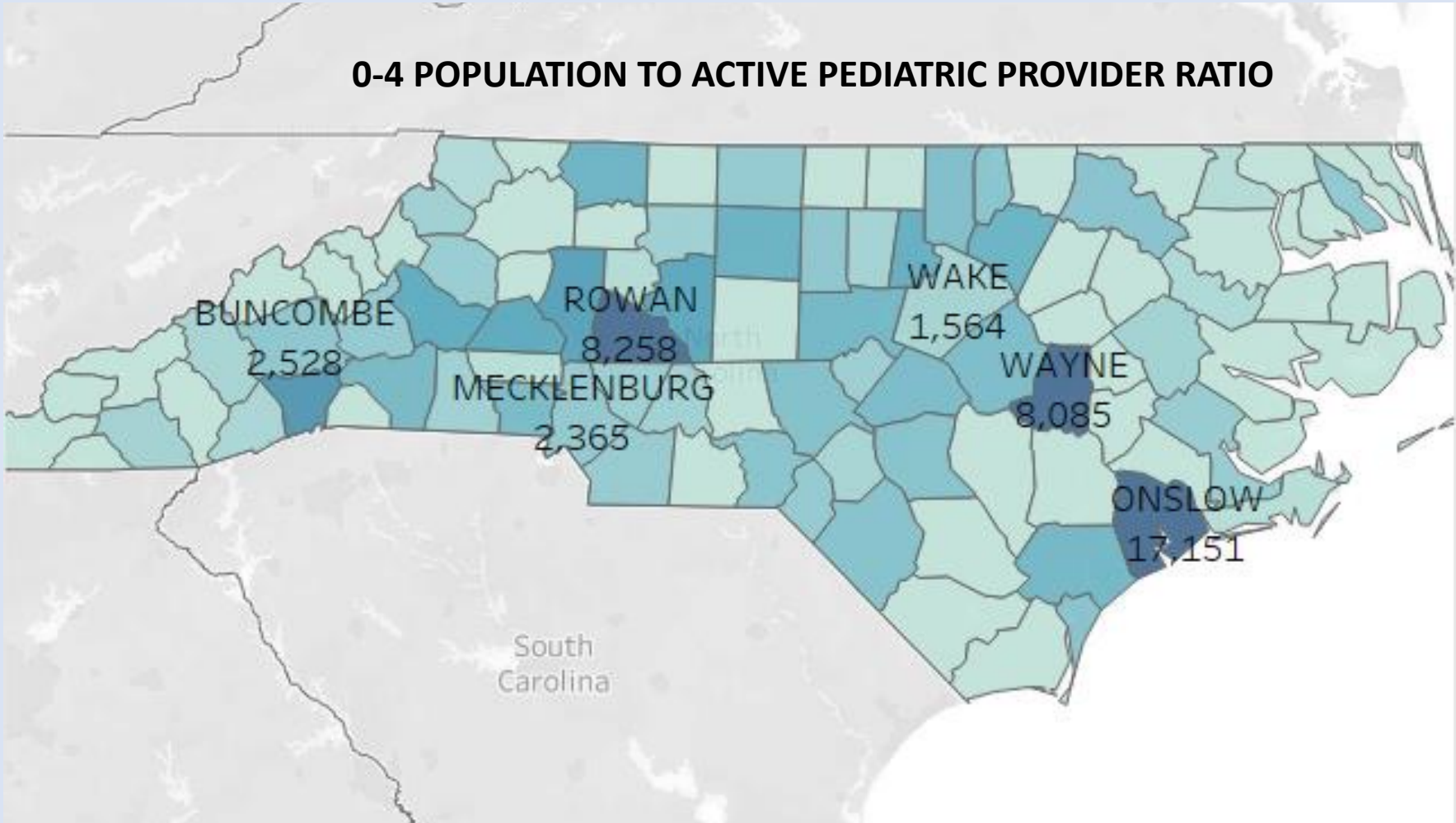
- The U.S. Food and Drug Administration has been notified by Pfizer that new data have recently emerged regarding its EUA request for the use of the Pfizer-BioNTech COVID-19 Vaccine in children 6 months through 4 years of age.
- The FDA is now delaying next steps of the authorization process for the Pfizer-BioNTech COVID-19 vaccine for children in this age group.

Implications on Ordering:



- Wave 1 orders for the Pfizer 6 months – 4 years vaccine placed last week has been canceled by the CDC. **There is no action required on your part to cancel these orders.**
- Should the Pfizer 6 months – 4 years vaccine become available again in the Spring, we will communicate the ordering process and next steps.

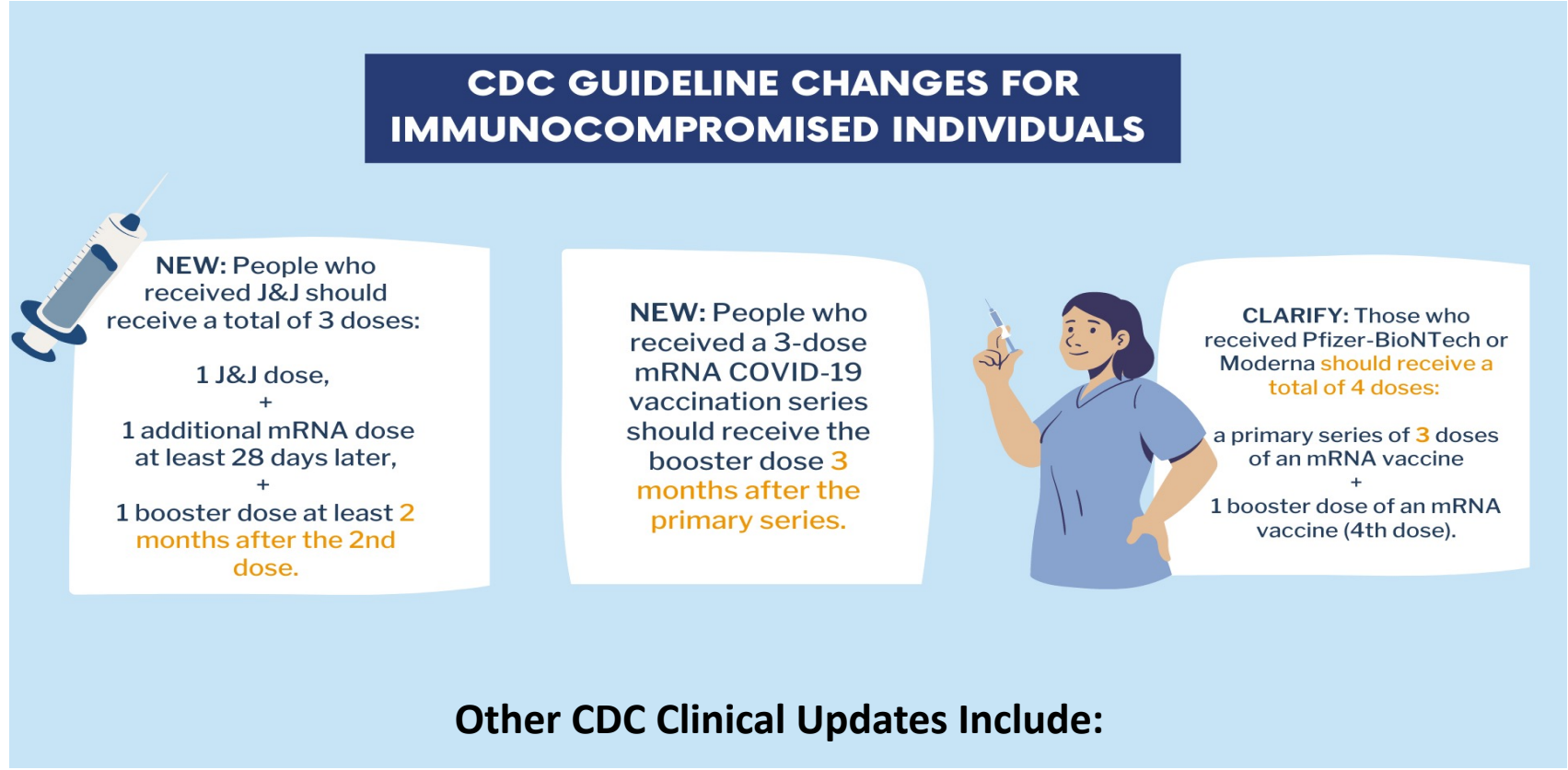
COUNTY PROVIDER COVERAGE



- Map shows the number of children between 0 - 4-year-olds per active pediatric provider in each county
- Darker counties have less providers serving a proportional number of the population
- The state will be following up with counties that have low provider coverage and a relatively high 6 month - 4-year-old population

*Population data sourced from 2019 population records and active pediatric provider counts sourced from CVMS data pulls

CDC GUIDANCE UPDATES FOR IMMUNOCOMPROMISED INDIVIDUALS



CDC GUIDELINE CHANGES FOR IMMUNOCOMPROMISED INDIVIDUALS


NEW: People who received J&J should receive a total of 3 doses:

- 1 J&J dose,
- + 1 additional mRNA dose at least 28 days later,
- + 1 booster dose at least 2 months after the 2nd dose.

NEW: People who received a 3-dose mRNA COVID-19 vaccination series should receive the booster dose 3 months after the primary series.

CLARIFY: Those who received Pfizer-BioNTech or Moderna should receive a total of 4 doses:

- a primary series of 3 doses of an mRNA vaccine
- + 1 booster dose of an mRNA vaccine (4th dose).



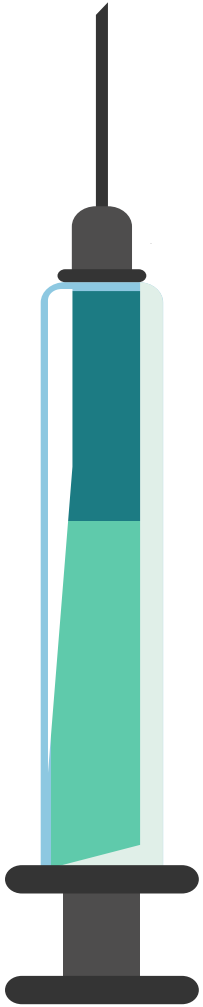
Other CDC Clinical Updates Include:

It is no longer necessary to delay COVID-19 vaccination following receipt of monoclonal antibodies or convalescent plasma.

Updated guidance on receiving a booster dose if vaccinated outside the United States.

Updated contraindication and precaution section to include history of myocarditis or pericarditis after an mRNA COVID-19 vaccine.

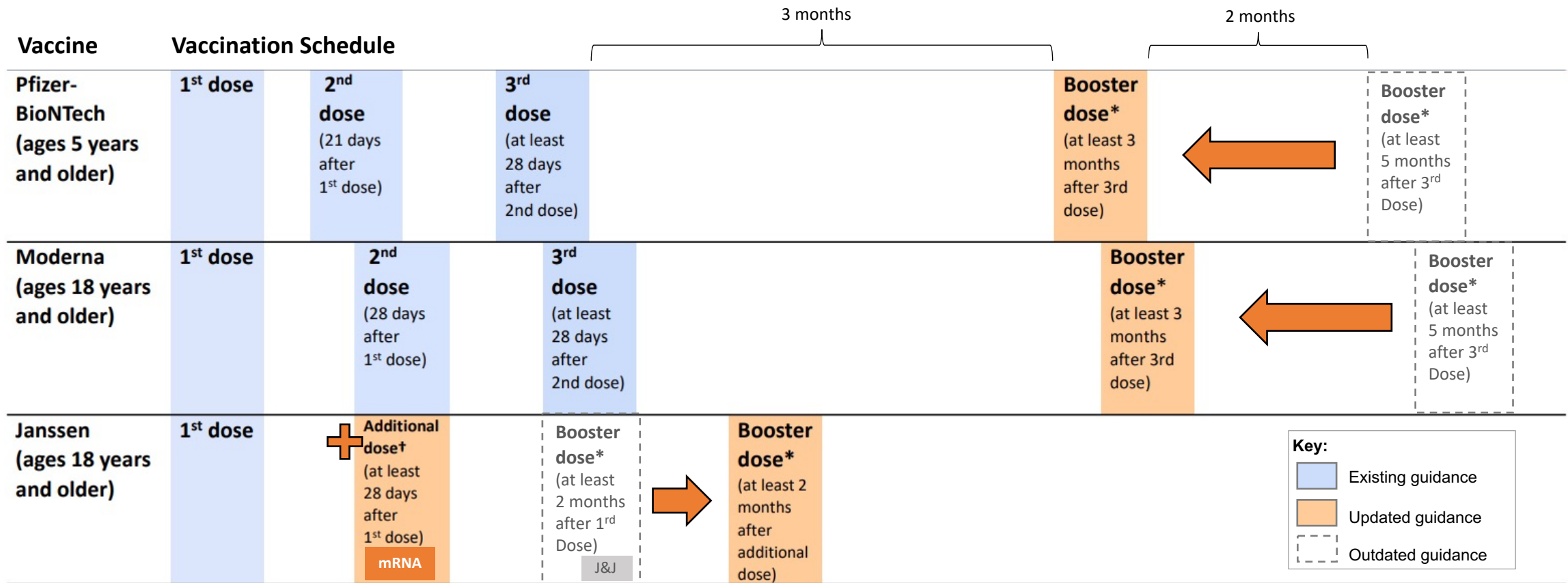
The latest versions of all Statewide Standing Orders can always be found [here](#).



MODERATELY OR SEVERELY IMMUNOCOMPROMISED – REVISED BOOSTER SCHEDULE

Key Takeaways:

- Pfizer & Moderna Booster Interval shortened to 3 months after 3rd Dose for Immunocompromised populations
- Additional (mRNA) dose recommended after Janssen primary series



*Any COVID-19 vaccine can be used for the booster dose in people ages 18 years and older, though mRNA vaccines are preferred. For people ages 12–17 years, only Pfizer-BioNTech can be used. People ages 5–11 years should not receive a booster dose.
 †Only Pfizer-BioNTech or Moderna COVID-19 Vaccine should be used

PFIZER 5-11 UPDATE AS OF 02/17

228,648 pediatric 1st doses and 192,513 pediatric 2nd doses have been administered.

Race	Adminned doses	% of total 1 st dose admin	% of total 2 nd dose admin	% of Race in State*
White	222,464	51.6%	54.3%	66%
Black or AA	73,242	18.2%	16.4%	27%
Asian or Pacific Islander	35,416	8.3%	8.6%	4.6%
American Indian or Alaska Native	3,335	.8%	.8%	2.4%
Other	39,700	9.8%	9.0%	-
Missing or Undisclosed	47,030	11.3%	11.0%	-

Ethnicity	Admin doses	% of total 1 st dose admin	% of total 2 nd dose admin	% of Ethnicity in State*
Not Hispanic or Latino	305,367	71.8%	73.3%	83%
Hispanic or Latino	50,816	12.7%	11.3%	17%
Missing or Undisclosed	65,002	15.5%	15.3%	-

Top Counties by Recipient	% of Pede Population with 1 st shot	% of total 1 st dose admin
Orange	65.0%	3.2%
Wake	46.3%	20.9%
Durham	44.1%	4.9%
Watauga	37.2%	.45%
Buncombe	34.4%	2.8%

Type of facility	Administered Doses	% of Total admin
Pharmacy (Chain)	140,557	33%
Pediatric Serving PCPs	118,217	28%
LHD	47,622	11%
Urgent Care	28,961	7%
Pharmacy (Independent)	25,308	6%
Others	66,943	16%

Key Takeaways

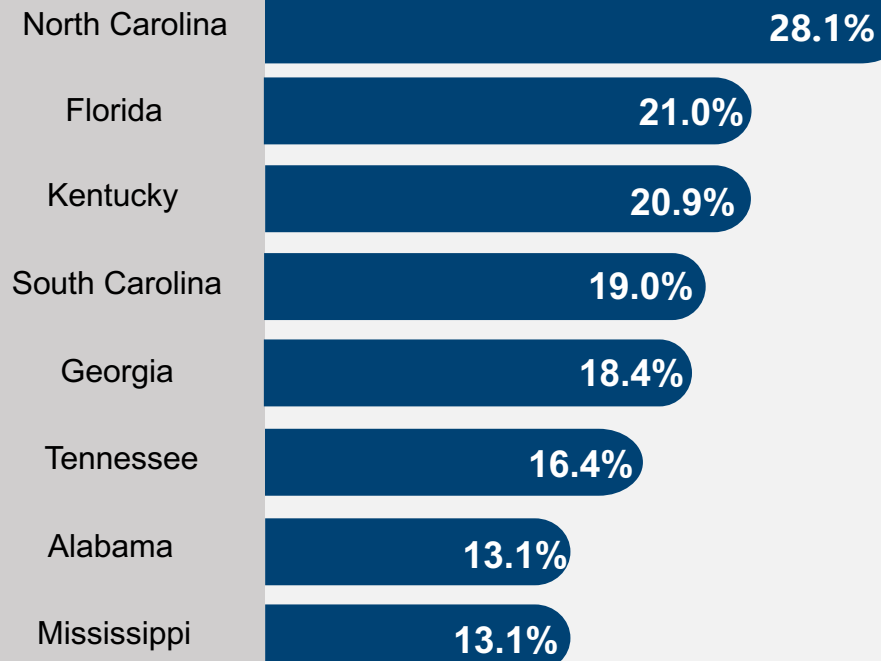
- We are seeing a much lower vaccination rate among Black or African American and Hispanic or Latino pediatric populations. 2nd dose administration for this population will be monitored as equity gap persists.

* % breakdown on kids ages 5-11

Source: BIDP as of 8:00 AM 2/17

PEDIATRIC VACCINATION RATES

North Carolina has the highest pediatric vaccination rate of FEMA IV States

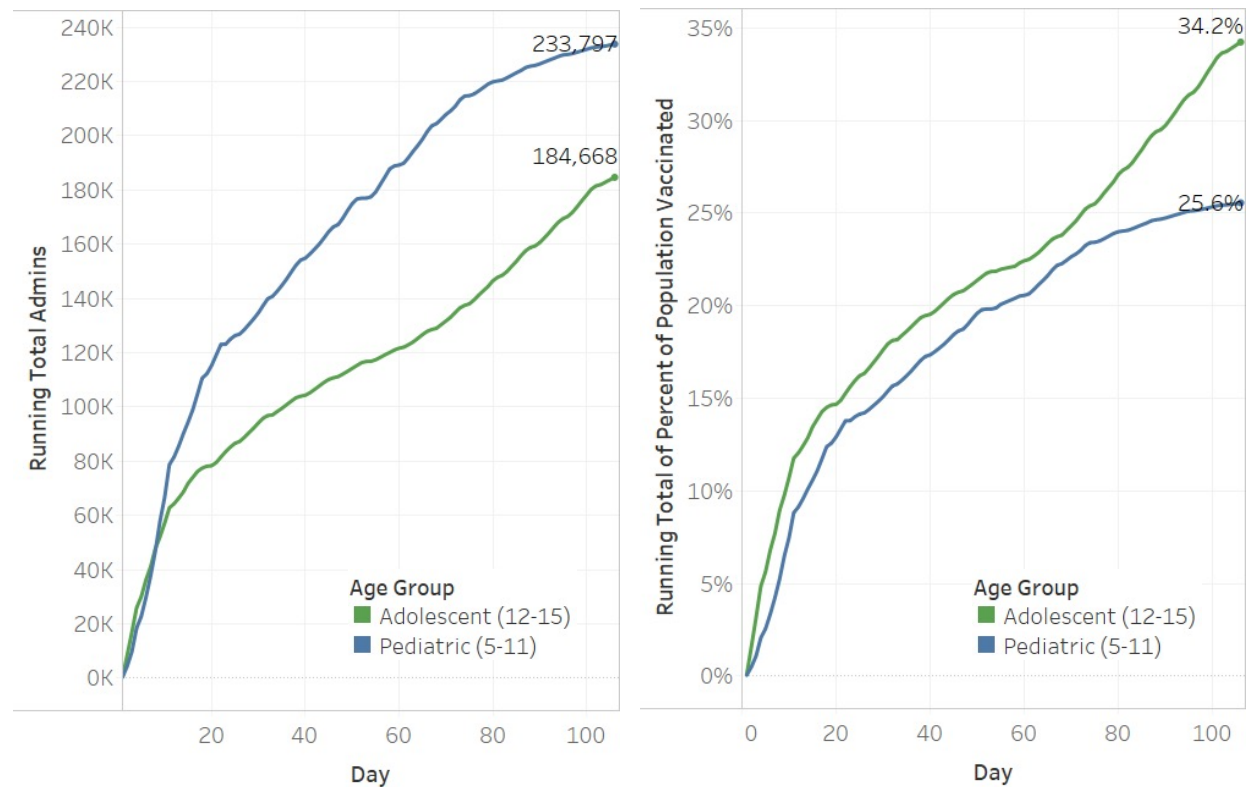


Source: All metrics are from 2/9/22 ASPR Report

Note: FEMA IV states shown are states with comparable vaccine programs.

The pediatric vaccination rate lags behind the rate of adolescent vaccination

Day 1 is regarded as first day CDC deemed each age group eligible for COVID vaccination.



Note: Day 1 is May 12, 2021 for adolescents and November 3, 2021 for pediatrics.

Dose 1 Only, Data from BIDP through 2/16/2022

WHAT WE'RE DOING: A VIAL IN EVERY FRIDGE



A SHOT IN EVERY ARM ISN'T POSSIBLE WITHOUT



Moving from mass vaccination → vaccine in house 24/7
Ensuring we never miss an opportunity to vaccinate

77%

% of parents say they trust their child's **pediatrician** to provide **reliable information** on vaccines for children*

44%

% of the unvaccinated that would feel **most comfortable** getting vaccinated at their **doctor's office****


46%

% of parents with an unvaccinated child aged 5-11 who say hearing from people they trust would make them much more likely to get their child vaccinated

100%

Of locations with vaccine on hand = 0% missed opportunities to counsel, validate, and vaccinate

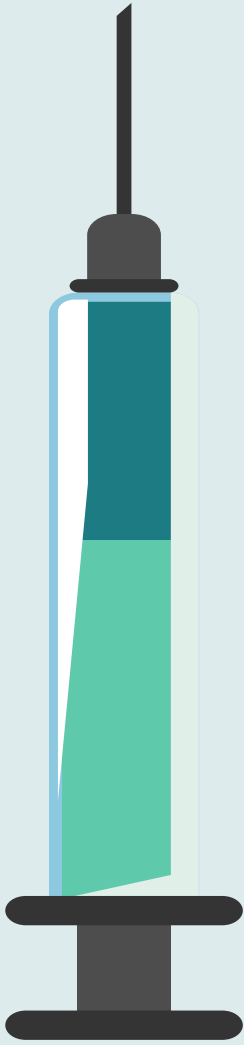
STATUS OF COVID-19 VACCINE AUTHORIZATION IN US: 1/31/22

	Adults 18 +	Pediatrics				Additional Dose <i>(Immunocompromised)</i>	Booster*
		16-17	12-15	5-11	6 months - 5 years		
	Approved (August '21)	Approved (August '21)	EUA (May '21)	EUA (May '21)	EUA Package Review – ON HOLD	EUA for 5+ yrs (Aug '21 – Jan '22)	EUA for those 12+ yrs at 5+ months
	Approved (Jan '22)	Under Review (June '21)	Under Review (June '21)	-	-	EUA for 18+ (Aug '21)	EUA for those 18+ yrs at 5+ months
	EUA (Feb '21)	-	-	-	-	N/A	EUA for those 18+ yrs at 2+ months
	-	Under Review (Nov '21)	Under Review (Nov '21)	Under Review (Nov '21)	Under Review for 2+ yrs. (Nov '21)		

*Mix and Matching permitted as of October '21 for those 18+

EUA = Emergency Use Authorization

FDA APPROVES MODERNA COVID-19 VACCINE



The Moderna COVID-19 Vaccine has been [approved by the FDA](#) and will now be marketed as **Spikevax** for the prevention of COVID-19 in individuals 18 years of age and older.

ACIP will be meeting on Friday to formally review the data and discuss approval of the vaccine for use in the United States.



What this Means for You

Spikevax has the **same formulation** as the EUA Moderna COVID-19 Vaccine



Spikevax can be used **interchangeably with existing on-hand EUA Moderna COVID-19 Vaccine** to provide the COVID-19 primary vaccination series and subsequent booster doses.



Moderna COVID-19 Vaccine **remains available** under EUA for primary series vaccination as well as booster vaccinations.