AGENDA MATERIAL
DATE 11/2/21 ITEM NO. RA 10

MEMORANDUM

Date: October 28, 2021

To: The Honorable Chair and Members
Pima County Board of Supervisors

From: Jan Lesher
Chief Deputy
County Administrator

Re: **COVID-19 Update for the November 2, 2021 Board of Supervisors Meeting**

Pandemic Update

Weekly COVID-19 case numbers in Pima County have plateaued at a relatively high-level with about 2,000 cases last week compared to a nadir of 243 cases during the last week in May. (Attachment 1) That puts our weekly rate at 212 cases per 100,000 (compared to 23 per 100,000 persons at the end of May).

Diagnostic testing for COVID-19 has increased during this surge as would be expected with 27,752 tests performed last week. Test positivity remained high last week at 10 percent, (compared to 2 percent during the prior low point during last week of May).

COVID-19 positive individuals occupy approximately 313 hospital beds each day this week. Overall intensive care capacity continues to be constrained across Pima County hovering at less than 5 percent adult ICU bed availability for a second month. This is due to a combination of factors including: 1) seasonal increases associated with fall and winter; 2) the scarcity of nursing personnel across the country; and 3) the impact of COVID-19 cases which have a higher level of acuity and prolonged length of stay. As of yesterday, intensive care bed use by COVID-19 patients occupied 23 percent of all ICU beds in Pima County.

Schools Update

Cumulative school reported cases since July 20 of this year are up to 3,513 as of last week. Students still represent the overwhelming majority of these cases at 87 percent compared to teachers and staff at 13 percent. Non-vaccine eligible children up to 11 years of age represent 47 percent (1,672 cases) of school reported cases, while the 12 to 19 year age group make up 39 percent (1,371 cases) of school reported cases. (Attachment 2)

Since the beginning of the school year 281 schools have reported cases. Among these, 105 had school outbreaks using the Centers for Disease Control and Prevention (CDC) definition (2 or more epidemiologically linked cases not in the same household), resulting in 62 separate classroom closures.

Vaccine Coverage

Delivering vaccine efficiently and equitably throughout Pima County has been a priority for the Health Department. The large scale PODS and retail pharmacies have been a critical component in achieving a substantial level of coverage within a relatively short period of time. Additionally, substantial resources and effort have been invested in decreasing barriers to that segment of the population that has not been served through those routes. In fact, the Health Department has invested considerable effort specifically to identify the most vulnerable census tracts and place vaccination in those communities through mobile and pop-up events and partnerships with school districts and federally qualified health centers.

This collaborative effort with our partners and contractors has reached individuals throughout Pima County in settings as diverse as churches, community centers, homeless shelters, schools, grocery stores, malls, barber shops, parking lots and the residences of the homebound. Federally Qualified Health Center partners have been critical in our efforts to reach vulnerable communities in urban and rural sites geographically dispersed throughout our community. In total such concerted effort has delivered in excess of 133,835 doses to Pima County residents at more than 900 events and locations.

Partner/Contractor	Doses Delivered
El Rio Health Center	*36,202*
Desert Senita CHC	*3,049*
United CHC	*12,532*
Marana Healthcare	*21,658*
Premier Medical Group	*41,471*
Paradigm Laboratories	*18,920*

The net impact of all these efforts is that 1,305,790 doses have been administered in Pima County. At this time, 78.2 percent of Pima County vaccine age eligible (12 years of age or older) residents have received at least a single dose COVID-19 vaccine, and 68.7 percent have been fully vaccinated. First dose coverage now exceeds 73 percent across all age groups, except for 10 to 14 (34 percent), 15 to 19 (59 percent), and 20 to 29 (56 percent).

In collaboration with the Information Technology Department, Health maintains and interactive website that is able to provide vaccine coverage information by census tract, jurisdictional boundary, school district, supervisory district and zip code. Despite areas of substantial social vulnerability, Pima County continues to have higher vaccination coverage rates compared to the rest of the state and the nation. (Attachment 3)

Booster and Pediatric Vaccination

"Booster" vaccinations are being distributed throughout the Pima County. This has been primarily through retail pharmacies, clinical providers and our Health Department. In the latter, boosters are available at the Abrams Public Health Department Building, all three County Health Department Clinics and at mobile sites throughout the community in partnership with our contractors. At this time more than 48,236 Pima County residents have received booster doses through these many efforts. Updated information is always available on our Health Department COVID-19 webpage including FAQs developed for distribution. (Attachment 4)

Additionally, in anticipation of forthcoming FDA and CDC approval of pediatric dosing for the Pfizer/Biotech vaccine, the Health Department has prepared a draft Pediatric Vaccination plan that specifically addresses the unique needs of 88,040 individuals that comprise the 5-to-11 population in Pima County. (Attachment 5) This document delineates in detail the strategies and approaches that will be activated upon approval of the vaccine by the federal government to meet the needs of children in this community. One element of the plan has already been set into motion with the request for allocation of 11,400 pediatric doses on behalf of 15 local vaccinators. These could arrive as early as the first week of November to be prepositioned for distribution as soon as the CDC authorization is received.

Conclusion

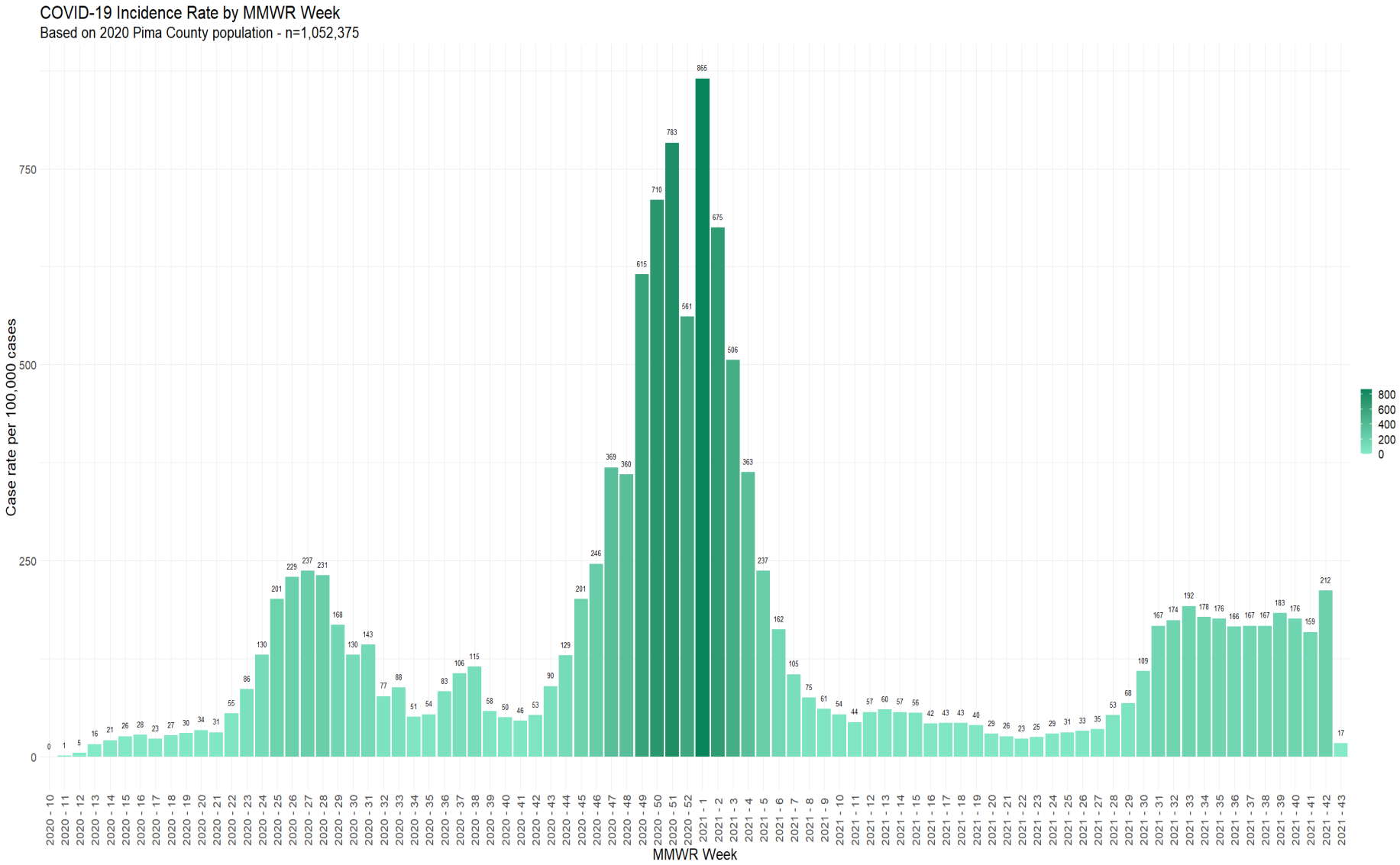
The pandemic appears to have plateaued in Pima County. The Health Department continues to invest heavily in vaccination and testing as its primary strategies to mitigate the COVID-19 infection in this community. Vigilance is still indicated during this time, even as we begin to fatigue of the important mitigation measures that we must continue to practice: mask use in public indoor spaces, avoiding work or school when sick, and maintaining physical distance from those outside our household.

JKL/dym

Attachments

c: Francisco García, MD, MPH, Deputy County Administrator & Chief Medical Officer, Health and Community Services
Carmine DeBonis, Jr., Deputy County Administrator for Public Works
Terry Cullen, MD, MS, Public Health Director, Health Department

ATTACHMENT 1


COVID-19 Incidence Rate by MMWR Week
Based on 2020 Pima County population - n=1,052,375
Case rate per 100,000 cases
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250
500
750
MMWR Week
2020 - 10
2020 - 11
2020 - 12
2020 - 13
2020 - 14
2020 - 15
2020 - 16
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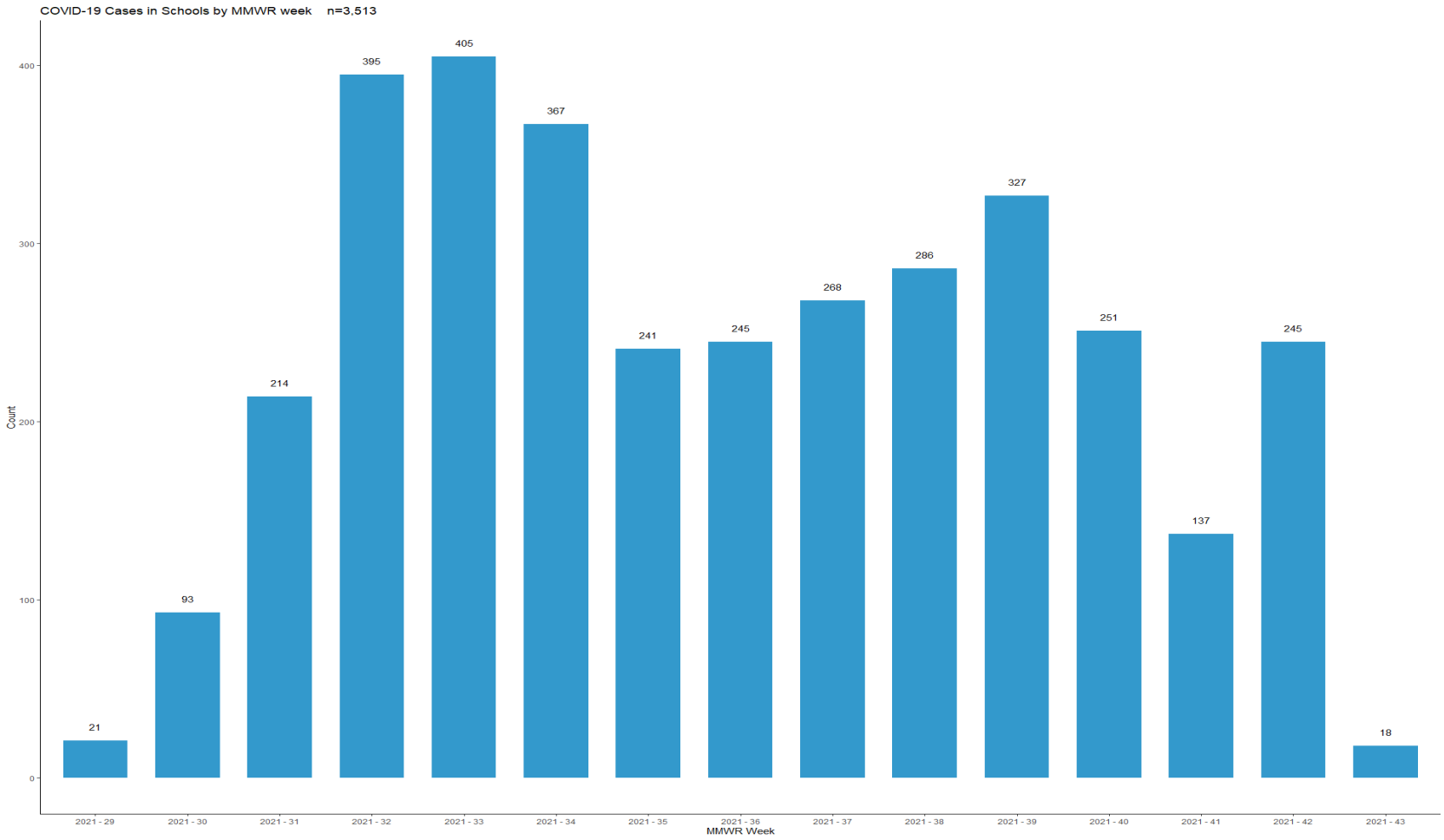
600
400
200
0

ATTACHMENT 2

PIMA COUNTY
HEALTH DEPARTMENT

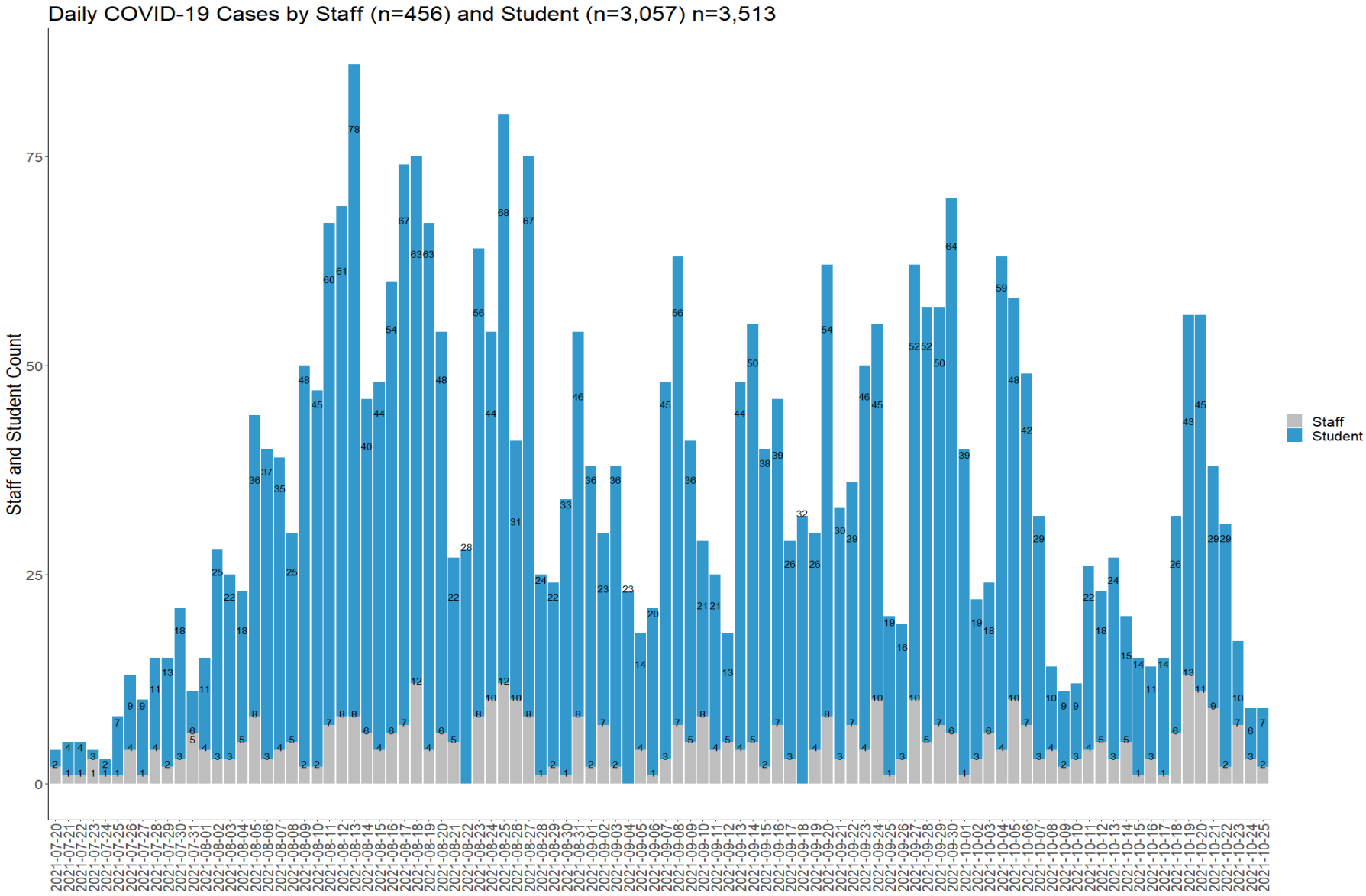
Thursday, October 28, 2021

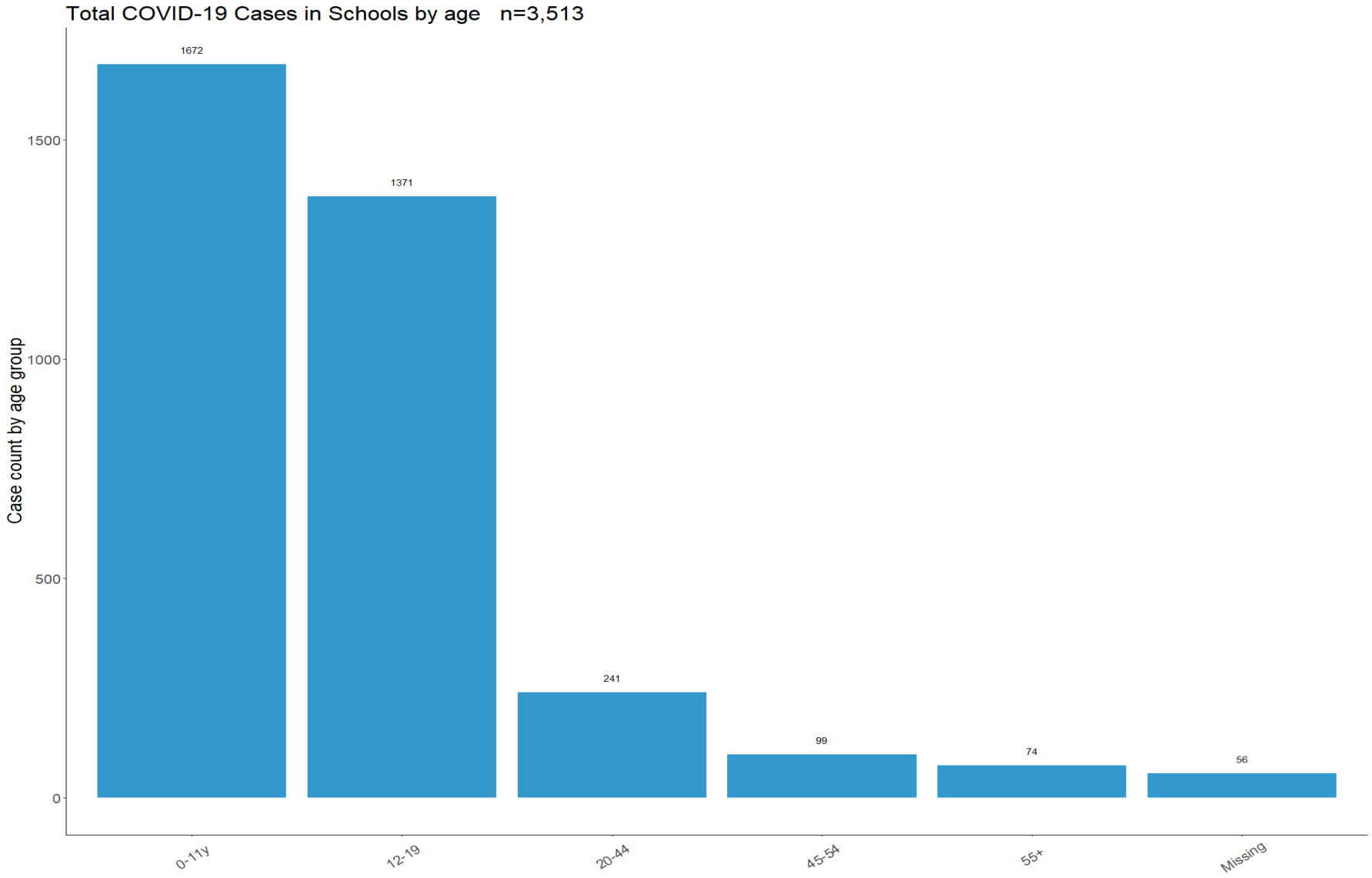
COVID-19 in Pima County Schools

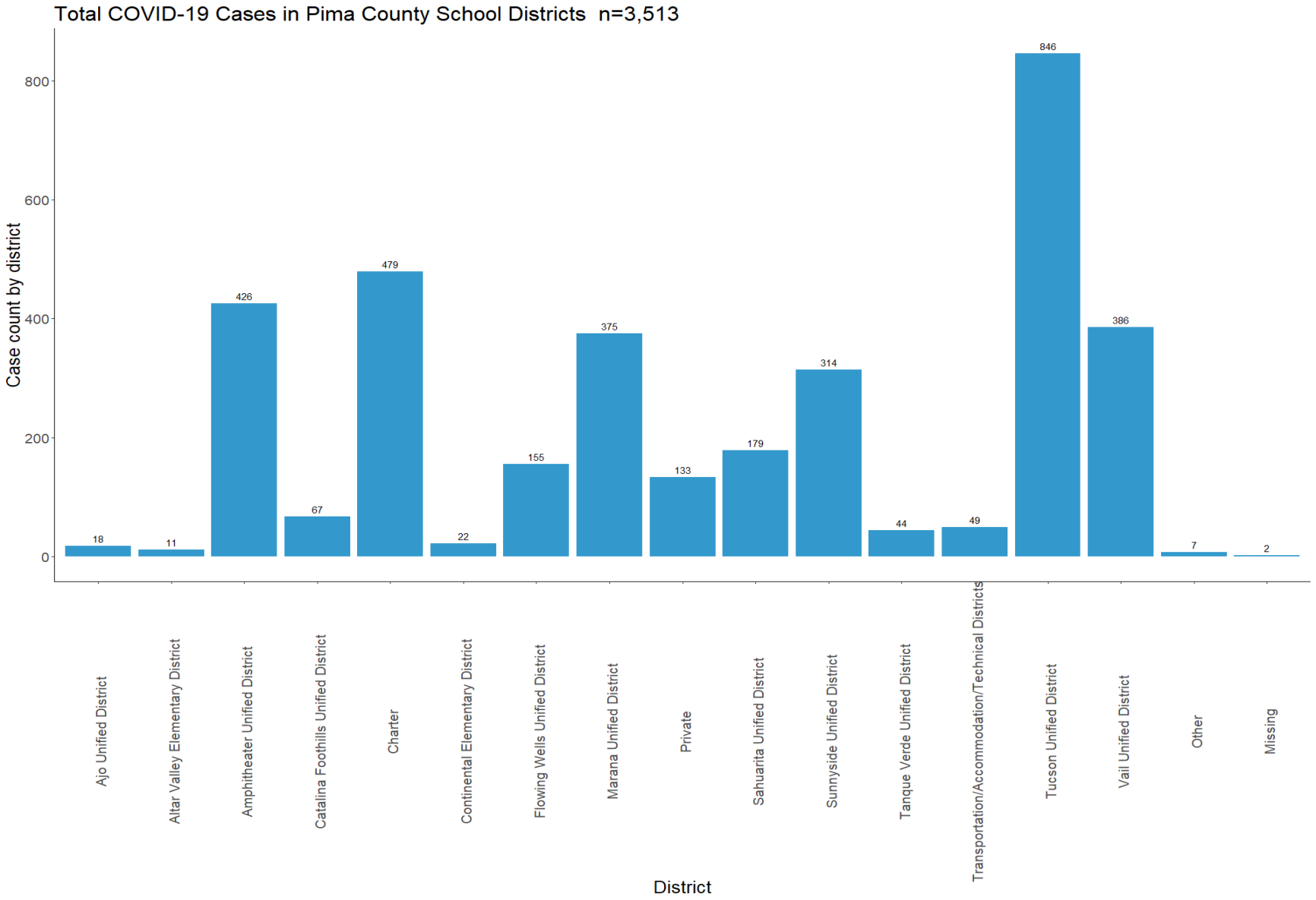


PIMA COUNTY
HEALTH DEPARTMENT

Thursday, October 28, 2021



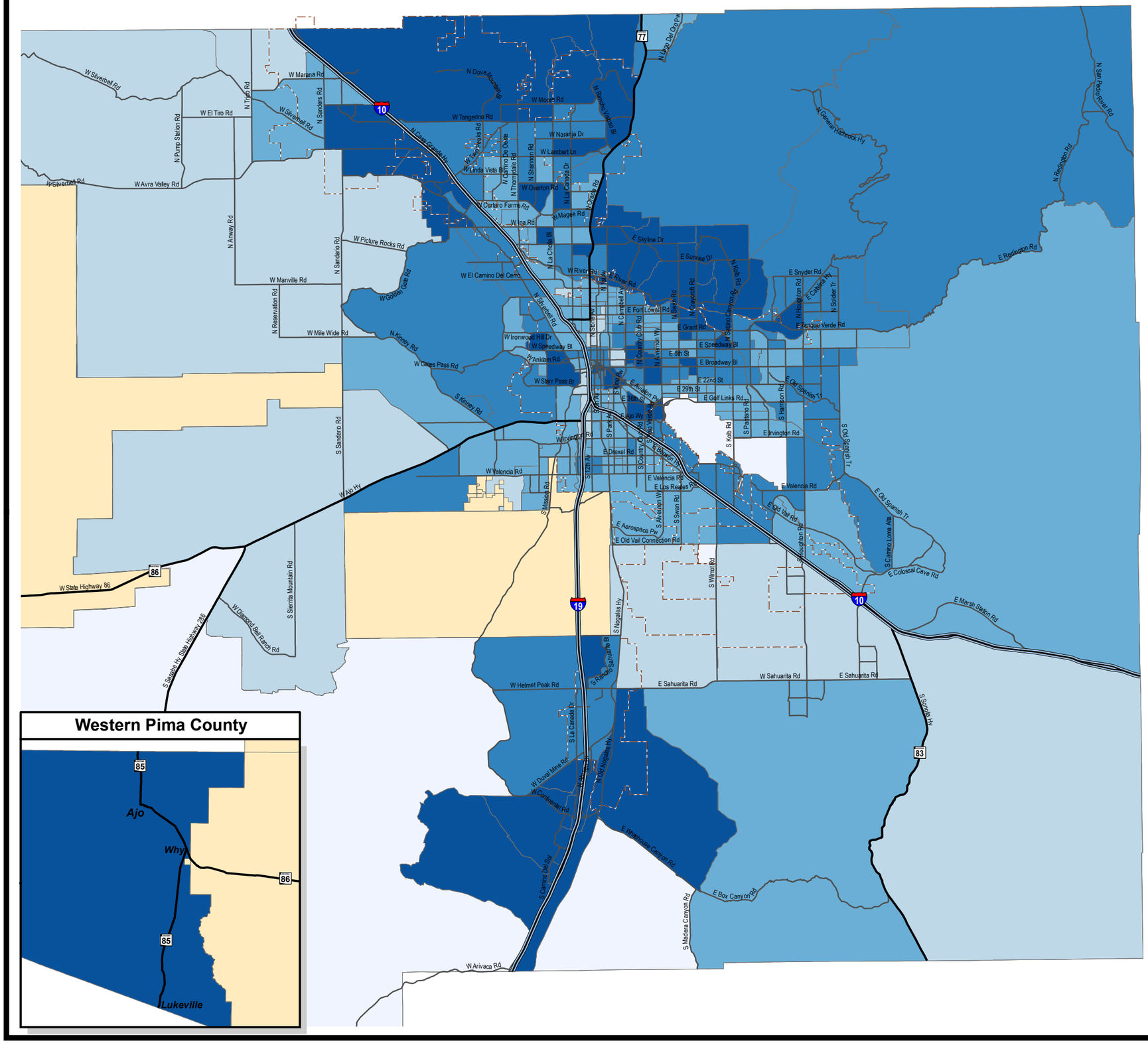

Total COVID-19 Cases in Schools by age n=3,513
Case count by age group
0
500
1000
1500
1672
1371
241
99
74
56
0-11y
12-19
20-44
45-54
55+
Missing


Total COVID-19 Cases in Pima County School Districts n=3,513
Case count by district
0
200
400
600
800
18
11
426
67
479
22
155
375
133
179
314
44
49
846
386
7
2
Ajo Unified District
Altar Valley Elementary District
Amphitheater Unified District
Catalina Foothills Unified District
Charter
Continental Elementary District
Flowing Wells Unified District
Marana Unified District
Private
Sahuarita Unified District
Sunnyside Unified District
Tanque Verde Unified District
Transportation/Accommodation/Technical Districts
Tucson Unified District
Vail Unified District
Other
Missing
District

ATTACHMENT 3

Rate of Completed COVID-19 Vaccination Series by Census Tract Through October 26

(Percentage of Tract Population Age 18 and Over that has Received Second Dose of Pfizer or Moderna, or First Dose of Johnson and Johnson)



Vaccination Rate

Selected Doses Given to 18+ / 2020 Population 18+

- < 33.0%
- 33.0% - 49.9%
- 50.0% - 64.9%
- 65.0% - 74.9%
- 75.0% - 100.0%
- **Tribal Lands**

N

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Miles

PIMA COUNTY
INFORMATION TECHNOLOGY
GEOGRAPHIC INFORMATION SYSTEMS

Pima County
Information Technology Department
33 N Stone Ave, 15th Floor
Tucson, AZ 85701-1207
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10/28/2021

ATTACHMENT 4

PIMA COUNTY
HEALTH DEPARTMENT

COVID-19 Boosters FAQs

What is a vaccine "booster" dose?
A booster dose is simply another vaccine dose given to someone who had already built up protection from a vaccine, but as time goes on, may need to have these levels "boosted" back into protective ranges. Tetanus, measles, mumps, rubella, and pertussis (whooping cough) are examples of other diseases for which booster doses are commonly given.

When should Pfizer or Moderna recipients get a booster?
The following groups are eligible for a booster if it has been six months or more since full vaccination with either the Pfizer or Moderna vaccines:

- People 65 and older.
- People 18 and older:
    - Who live in long-term care settings. (Examples include skilled nursing and assisted living facilities, and residential care settings.)
    - Who have underlying medical conditions. (Examples may include cancer, kidney, liver, heart or lung, or immunocompromising illnesses.)
    - Who work or live in high-risk settings. (Examples of workers may include people employed in positions as first responders, education staff, food or grocery store staff, public transit, correctional, and post office staff. Examples of high-risk settings may include health care, schools, correctional facilities, and homeless shelters.)

What about people who got the Johnson & Johnson vaccine?
It is recommended that anyone 18 and older who initially received the Johnson & Johnson vaccine get a booster shot at least two months after their initial vaccine.

What about immunocompromised people who received a third dose as part of their primary series?
Moderately and severely immunocompromised people 18 and over who received a third dose of Moderna or Pfizer as part of their primary series at least six months ago may receive a single booster dose with any of the available vaccines. Moderately to severely immunocompromised people 18 and over who received a single dose of the Johnson & Johnson vaccine as part of their primary series should receive a single booster dose with either Pfizer, Moderna, or Johnson & Johnson at least two months after vaccination. People who are moderately to severely immunocompromised are those with weakened immune systems due to conditions including cancer treatments, organ transplants, immune deficiencies, or treatment with immune-suppressing medications.

Does the booster have to be the same brand as the original series?
People have the option to select a brand that is different from the vaccine they originally received. The CDC encourages people to discuss the benefits and risks of each product with their healthcare provider to determine which booster is most appropriate for them.

How long after a recent COVID-19 infection can I get a booster?
People who have had COVID-19 should wait until they have recovered from the acute illness if they had symptoms, and have met the criteria to end isolation. For most people, this is 10 days after a positive test.

What kind of a reaction should I expect?
The side effects people have reported with boosters have been similar to those reported after the two-shot series. Overall, most side effects are mild to moderate, with fatigue and pain at the injection site most commonly reported. Some people may experience headache, fever, and muscle pain.

Do I have to pay for the booster?
No, as with the primary vaccine series, you do not have to pay for the COVID-19 booster.

Will I need another booster in the future?
It is unknown at this time if future boosters (similar to the yearly flu vaccine) will be needed.

Where are booster shots available?
All three vaccine booster types are widely available across Pima County from a variety of retail pharmacy and clinical providers. They are also available at Pima County Public Health Clinics (First Avenue and Prince, Midvale Park, Broadway and Pantano, Ajo and Country Club) as well as various mobile sites. Find locations and hours of operation for County sites at www.pima.gov/covid19vaccine. Check vaccines.gov for availability at pharmacies.

These recommendations are accurate as of Oct. 26, 2021, and will be updated as more information is available.

Sources:
CDC Expands Eligibility for COVID-19 Booster Shots CDC, 10/21/21
Who Is Eligible for a COVID-19 Vaccine Booster Shot? CDC, 10/22/2
Possible Side Effects After Getting a COVID-19 Vaccine CDC, 9/30/21
Interim Clinical Considerations for Use of COVID-19 Vaccines Currently Approved or Authorized in the United States CDC, updated frequently

ATTACHMENT 5

PIMA COUNTY
COVID-19 VACCINATION PLAN
FOR CHILDREN AGED 5-11

Supplement to Accelerated Immunization Plan

Prepared by the
Pima County, Arizona
Health Department

October 27, 2021

PIMA COUNTY
HEALTH DEPARTMENT

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ACCELERATING COVID-19 IMMUNIZATION IN PIMA COUNTY

I. INTRODUCTION

The Pima County Health Department (PCHD) expects the U.S. Food and Drug Administration (FDA) to issue an Emergency Use Authorization (EUA) for the Pfizer-BioNTech COVID-19 vaccine for children aged 5-11, which will then lead to approval by the CDC. In anticipation of this eventuality, PCHD has developed the *Pima County COVID-19 Vaccination Plan for Children Aged 5-11* (the Plan) to ensure the ethical and equitable distribution of this vaccine to children aged 5-11. As other vaccines are approved for this age group, the Plan will expand to include them.

Layered mitigation measures such as social distancing, masks, and remote schooling have been recommended for all children during the pandemic. With authorization of the COVID-19 vaccine for children aged 5-11, vaccines will be available as an additional measure to protect individuals, families, and communities and help limit the spread of COVID-19.

Statement of Purpose

This Plan outlines strategies to be used to assure vaccine access and equity to Pima County residents aged 5-11.

Problem Statement

Existing inequities coupled with other social determinants of health have contributed to historical health disparities in Pima County. Ongoing delays in access to testing, care, and interventions have continued throughout the course of the COVID-19 pandemic. These disparities have affected all ages, including Pima County residents aged 5-11.

The vaccination of young children will face uptake challenges including addressing safety concerns and vaccine hesitancy among some parents and guardians. This is further exacerbated by confusion about the effect of pediatric COVID-19 illness, poor understanding of the long-term health impact of infection on children, and the role of children in disease transmission.

Scope

This plan augments the Pima County's *COVID-19 Accelerated Immunization Plan, Vaccine Equity for Vulnerable Populations in Pima County*, *COVID-19 Response Point of Dispensing Playbook*, *COVID-19 Phase 3 Strategic Communications Overview*, and *COVID-19 Booster Vaccination Plan* with countywide actions and messaging to drive the vaccination of children aged 5-11, prioritizing vulnerable and high-risk individuals in marginalized communities.

Strategy and Stakeholders

Multi-agency, cross-disciplinary advisory groups have been established with the mission to expeditiously and skillfully vaccinate in Pima County during all vaccination phases identified in the *CDC COVID-19 Vaccination Program Interim Operational Guidance for Jurisdictions Playbook*. These groups have developed and continue to implement a vaccination plan to meet

this goal, including defining the scope and designing risk/crisis response communication protocols.

II. BACKGROUND

As of October 2021, there have been nearly two million COVID-19 cases in children aged 5-11, over 8,000 hospitalizations, and over a hundred deaths nationwide. Arizona bears some of the highest cumulative pediatric COVID-19 cases and hospitalizations in the country. The expected approval of the Pfizer-BioNTech vaccine will allow eligibility expansion to children aged 5-11, protecting adults in contact with them as well as limiting the exposure of the vulnerable to transmission.

Pediatric Transmission

Despite early suggestions that the incidence rate of COVID-19 infection in children may be lower than adults, subsequent studies have shown COVID-19 infection and symptomatic illness in children may be comparable to adult rates. Transmission studies have shown that children may infect others in schools, camps, sports events, their households, and the general population.

Pediatric Infection

The impact of pediatric infection, especially by new variants, remains poorly understood. Though children with COVID-19 have lower hospitalization and ICU admission rates than adults, some children can face lasting health consequences of COVID-19 infection, up to and including death.

Studies suggest the acute and chronic health sequelae of pediatric COVID-19 infection may affect child and family functioning. Even transient anosmia, one of the most common COVID-19 side effects, could negatively impact the brain development of children. One study found that 22% of pediatric COVID-19 or multisystem inflammatory syndrome in children (MIS-C) patients had documented neurological involvement. Of these, 12% developed life-threatening neurological conditions.

While the prevalence of pediatric Long COVID is unclear, children do experience long-term sequelae such as MIS-C and may experience Long COVID. Asymptomatic children who tested positive for COVID-19 reported symptoms including insomnia, respiratory symptoms, nasal congestion, fatigue, muscle and joint pain, and difficulty concentrating. These symptoms can last six to eight months after clinical diagnosis of COVID-19.

Vaccine Hesitancy

Although the Pfizer-BioNTech vaccine for children aged 5-11 has been shown to have over 90% efficiency against symptomatic COVID-19, vaccine hesitancy affecting parents or guardians of children in this age group must be addressed.

Even before the pandemic, parents had greater vaccine hesitancy than non-parents. Today, the misinformation surrounding routine pediatric vaccination corresponds with parental hesitancy

toward pediatric COVID-19 vaccines. In other words, risk perceptions about pediatric COVID-19 and routine vaccinations may amplify one another.

The inverse may also be true: A focused effort to reduce the risk perception of the pediatric COVID-19 vaccine may build confidence in routine vaccinations. It may also provide opportunities to persuade unvaccinated parents and guardians.

Pediatricians, primary care physicians, and other childhood healthcare providers are crucial influencers in this effort. Evidence from prior vaccination campaigns show that patients are much more likely to receive a vaccination on a provider's recommendation than without.

Uptake Estimates

At time of writing, it is difficult to forecast with precision the number of monthly doses required for this age group. Nationally, the Kaiser Family Foundation estimates that approximately one third of parents or guardians will vaccinate their children aged 5-11 as soon as the vaccine becomes available. Of these, most will get a second dose. If uptake trends for children aged 5-11 match the experience in Pima County for adolescents aged 12-17, around 60% of the newly eligible population will seek vaccination after several months.

Table 1. Pima County Population Aged 5-11

Jurisdiction	Population
Marana	5,002
Oro Valley	2,943
Sahuarita	3,651
South Tucson	641
Tucson	47,238
Unincorporated Pima County	28,565
Total Eligible Population	**88,040**

Source: Esri Demographics, 2021

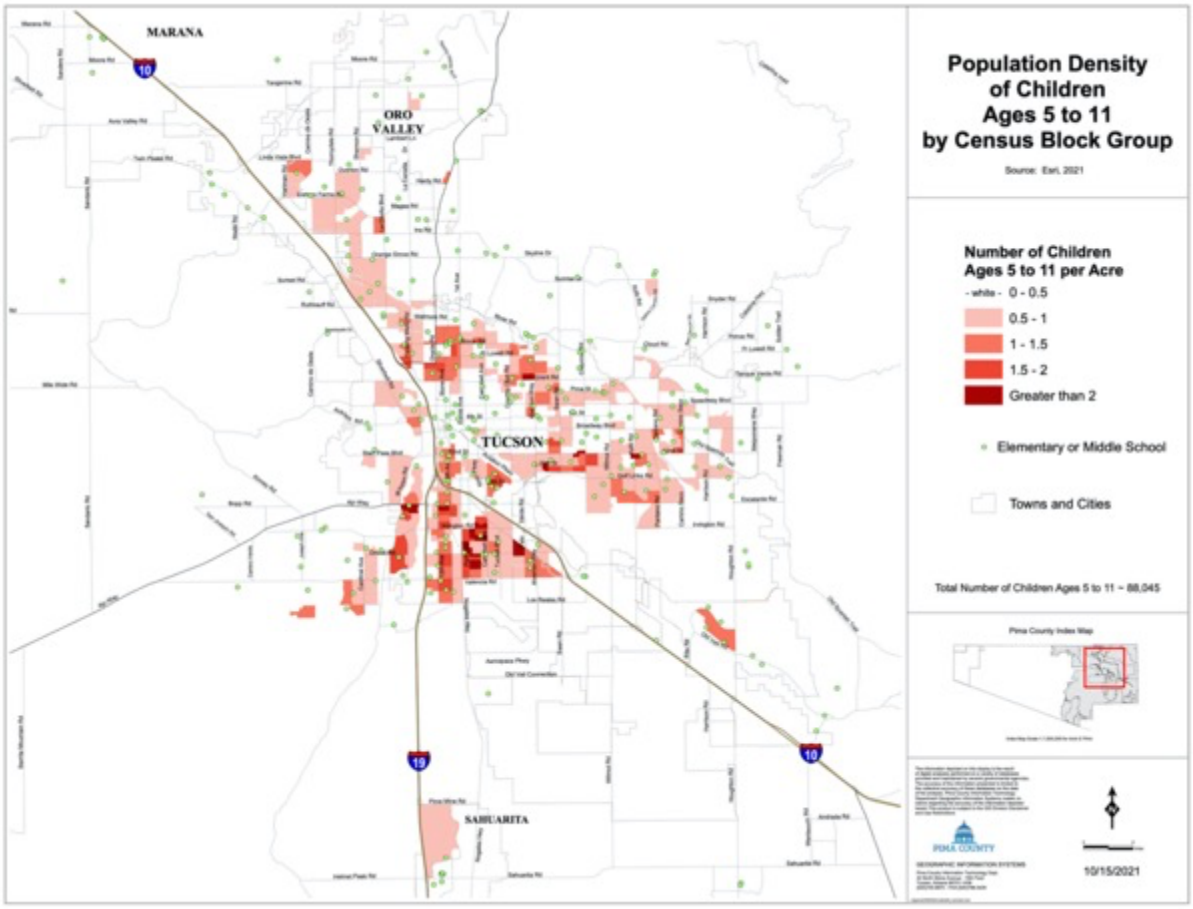
There are approximately 88,000 children aged 5-11 in Pima County (see Table 1). Taking into account the above trends and data available at time of writing, a reasonable estimate is that by February, the County will need a cumulative total of over 111,000 doses for delivery to children aged 5-11 years old (see Table 2).

Table 2. Estimated Uptake for Children Aged 5-11

	Nov '21	Dec '21	Jan '22	Feb '22
Estimated doses/month	22,000	35,000	25,000	20,000
Estimated cumulative doses required	22,000	57,000	82,000	102,000
Children 5-11 with first dose (% of total)	25%	41%	51%	60%
Fully vaccinated children 5-11 (% of total)	0%	28.8%	39%	50%

Source: KFF COVID-19 Vaccine Monitor: Vaccination Trends Among Children and COVID-19 In Schools. *Kaiser Family Foundation*. Published September 30, 2021. https://www.kff.org/coronavirus-covid-19/poll-finding/kff-covid-19-vaccine-monitor-trends-among-children-school

Figure 1. Population Density of Children Aged 5-11 by Census Tract



III. STRATEGIC ACTION PLAN

The expected emergency approval of the Pfizer-BioNTech vaccine promises relief to families and school-aged children who have been severely and disproportionately impacted by the pandemic. The Pima County Health Department is committed to:

- Equitably allocate sufficient doses to vaccinate all Pima County children aged 5-11.
- Equitably track and position vaccine sites to ensure that eligible individuals can receive vaccines in a safe and timely fashion.
- Provide evidence-based, unbiased information on vaccine safety, physical distancing, and mask wearing to maximize the impact of these vaccines.

The Pima County strategic action plan for COVID-19 vaccination of children aged 5-11 is a three-pronged approach to (1) **identify and prioritize** eligible individuals and communities, (2) engage those individuals and communities with a targeted **outreach and communication plan**, and (3) **administer the vaccines**.

Identify and Prioritize Children Aged 5-11

Despite the current activation of points of distribution across the County, a significant proportion of the population continues to face barriers to information, technology, and access to vaccination services. Key issues of concern have been noted above and include the inability for parents or guardians to navigate complex electronic registration requirements and/or lack of access to the vaccine clinics, either due to mobility issues and/or a lack of transportation.

This Plan augments existing plans with a multi-faceted approach to assure that communities within the County, especially the medically under-served, have equitable access to vaccinations.

According to the National Institutes of Health (NIH) *COVID-19 Treatment Guidelines*, immunocompromised children and children from communities of color may be at increased risk for severe COVID-19 illness. Other possible pediatric risk factors include:

- obesity
- chronic cardiopulmonary disease
- organ dysfunction
- long-term dependence on technological support
- other complicating medical conditions

The Plan will draw from this and other existing criteria, which prioritizes individuals in consideration of the recipient and census tract factors, outlined below, to maximize volume and equitability of vaccine administration. Vulnerable and high-risk communities are prioritized through the vaccine distribution map overlaid with Social Vulnerability Index (SVI). Specific community needs will continue to be assessed and accommodated with key issues of concern including mobility and transportation access.

- Recipient Factors
    - High risk chronic condition
    - Viral exposure
    - Social vulnerability
- Census Tract Factors
    - COVID-19 infection rate
    - COVID-19 mortality

Some children living with disabilities or high-risk medical conditions and significant functional limitations are unable to leave the home and require at-home vaccination. Identification and vaccination of these individuals will require targeted communications in collaboration with disability advocacy groups, community service organizations, pediatric home health providers, and existing outreach programs and networks.

Engage the Community

Relevant and intelligible communication that has been adapted to the cultural and linguistic needs of the targeted communities in a variety of media and formats is essential to implementing a successful pediatric vaccination program. Dispelling misinformation and building vaccine confidence is vital to ensuring uptake. Communication will be tailored for parents and guardians, schools, childcare facilities, pediatricians, and community partners. The information will be adapted to local needs and presented in plain language so that it is easily understood, as per Pima County Health Department's Cultural Competency AD-20 OPP.

Community Health Workers (CHWs) and other lay community members will support outreach efforts via canvassing, tabling, and other community engagement efforts. CHWs have been trained on talking points, including, but not limited to the following:

- Vaccine safety
- Vaccine efficacy
- Vaccines in communities of color (who was tested in vaccine trials)
- Understanding vaccine hesitancy and historical trauma in communities of color and historically marginalized groups
- Vaccine myths
- Common side effects
- What to do if side effects occur
- The second appointment
- Vaccine priority groups
- Vaccine cost
- Going back to "normal"
- Testing positive and getting the COVID vaccine
- CDC V-Safe smartphone
- Where to go and what to expect: "No ID required."
- Signing up for at home vaccination
- Resources addressing other social determinants of health (housing, transportation, food security, etc.)
- Language support and assistive communications at vaccine sites

Communication Objectives

- Engage **internal and external partners as well as parents or guardians** to understand their key concerns and needs related to the COVID-19 vaccine.
- Ensure accessible, effective, evidence-based, trauma-informed, and timely **messaging and outreach** adapted to the cultural and linguistic needs of the targeted community.
- Evaluate local attitudes, concerns, and knowledge regarding the COVID-19 vaccine and **respond to information needs.**
- **Follow up** with dose information ensuring those who receive the initial vaccine know when to return for the second dose.
- Increase **vaccine confidence** and reduce community members' hesitancy.
- Create **pictorial-based and video messaging** to reach youth and people with a variety of literacy levels.
- Increase messaging about vaccination from a **diverse array of voices.**
- Share the requirements of the consent process for children.

Communication Activities

- Engage with **Community Health Workers (CHWs)** to co-create and disseminate messaging.

- Engage existing **community partners** to co-brand outreach materials to reduce government mistrust by leveraging trusted relationships by non-governmental organizations with the community.
- Ensure all communication efforts meet the requirements for the Americans with Disabilities Act, the Rehabilitation Act, the Patient Protection and Affordable Care Act, the Plain Language Act, Culturally and Linguistically Appropriate Services (CLAS) Standards, and other disability rights laws for **accessibility**.
- Engage with a wide range of **partners**, collaborators, and utilize communication and news media channels to achieve communication goals.
- Establish a **webpage** on pima.gov as a one-stop shop for information including parent/guardian FAQs, vaccine encouragement videos, graphics, and other resources such as testing

Communication Outreach Action Items and Focuses

- Messages for **Parents/Guardians**
    - Studies show that the COVID vaccine is safe and effective.
    - Encourage parents or guardians to "give your kids their childhood back."
    - Engage with a wide range of partners, collaborators, and utilize communication and news media channels to achieve communication goals.
    - To be young and healthy is great, but others aren't. Get the vaccine for your friends and family.
    - Parents and guardians have an important role in the vaccine consent process.
- Engage **pediatricians and other childhood health care providers** as persuasive voices appealing to concerned parents and guardians.
    - Provide healthcare providers with material that will allow them to confidently address concerns from parents or guardians:
        - Evidence-based advice on vaccines
        - Information on out-of-pocket costs for the vaccine
        - Material to address parent or guardian concerns for needle pain, skin reactions, and sensitivity
        - Rapid antibody testing to show parents or guardians individualized evidence of their child's lack of protection from infection
- Educate **parents, guardians, teachers, and school administrators, and pharmacies** on what side effects may look like in younger populations through interactive events and publications.
    - Leverage pediatric voices as "trusted messengers" to promote vaccine uptake in minors.
- Work with **local schools** and districts to provide graphics and lesson plans on viruses and vaccines for student education to move towards herd immunity in schools.

- Partner with youth-serving **community organizations** including churches, YMCA, scouts, and others.

Administer Vaccine

Pima County has leveraged existing relationships with the 16 Pima County school districts to create a direct communication line at multiple levels of these organizations. These communication channels, used throughout the pandemic to expedite information sharing, have contributed to the ability to rapidly set up mobile vaccine clinics at school sites. All school sites have been contacted to be potential vaccination sites.

The County will host vaccine clinics at elementary schools, as well as Family Pfizer vaccine clinics on weekends to encourage a whole family event. PCHD has further implemented a homebound vaccination program that will be available to ensure that homebound children aged 5-11 will have access to immunizations if not available through their clinical provider. PCHD will also be working with State Medicaid to coordinate vaccinations.

Vaccine Clinics

Sites that have been identified for administration of Pfizer-BioNTech vaccine include:

- Current static vaccine clinics operated by PCHD and contractors
- Mobile vaccine clinics at Public, Charter, and Private School sites
- Other schools identified as priority community vaccination locations based on
    - Social Vulnerability Index (SVI)
    - Current COVID-19 vaccination rates
    - Sites that are hosting community events (sporting events, fall events, etc.)
- Provider practice locations for children aged 5-11
- Retail pharmacies

Vaccine Supply

To ensure efficient rollout of vaccine supply, providers should plan their ordering strategy now and identify the priority locations and sequence of activating these priority locations during the initial weeks of the pediatric vaccination efforts.

- Shipment for pediatric vaccines for children aged 5-11 will occur when the FDA issues the EUA. Vaccine administration can begin once the CDC Director makes a recommendation.
- For the initial roll out, a large distribution of pediatric product will be made available pro-rata for jurisdictions to pre-order through PCHD.
- PCHD is using the ADHS local allocator tool to place orders for Pima County providers.
- Pre-orders have occurred in three waves beginning October 20, 2021.
    - Allocation Cycle 1 started October 20, 2021.
    - Allocation Cycle 2 started on October 22, 2021.

- Allocation Cycle 3 started on October 24, 2021. This was the final prepositioning opportunity before moving to regular ordering through the Arizona State Immunization Information System.
- Pre-ordering through these waves will allow for a manageable and equitable launch for this new vaccine.

This large early supply will ensure that vaccine can be placed in many locations, making it easier for children to get vaccinated. Ordering caps have been imposed on jurisdictions and second dose plans are being developed. After this initial distribution, a weekly supply will be made available through the State to help sustain the network and support site specific needs as vaccine is administered.

The minimum order is 300 doses for program launch and 100 doses in subsequent weeks. Jurisdictions should account for these minimum order quantities when identifying the initial sequence of provider site activation for receipt of pediatric COVID-19 vaccine.

Not all COVID-19 vaccination sites will need to receive pediatric vaccines. Vaccination providers that are most likely to vaccinate pediatric populations should be prioritized, with provider types likely varying across communities (e.g., pediatric clinics, federally qualified health centers, pharmacies, rural health clinics).

Pharmacies participating in the Federal Retail Pharmacy Program will order vaccine to be delivered at select pharmacy locations, increasing the number of locations children may go to get vaccinated. Pharmacies selected locations within their network that can best manage supply and that are ready to administer vaccine to pediatric populations.

Pima County has further coordinated with childhood health providers, including Vaccines for Children (VFC) providers, who have been qualified and are prepared to deliver this immunization.

The public will be directed to use www.vaccines.gov to help find providers offering COVID-19 pediatric vaccines. Thus it is critical that all providers report pediatric vaccine supply to VaccineFinder so that their location may be displayed on www.vaccines.gov.

The U.S. government and the manufacturer will be providing additional training to prepare providers to administer vaccine to younger children; providers and locations will all need to be trained.

Communications

In addition to implementing the community engagement plan, the PCHD **communications team** will continue to support all static and mobile vaccine clinic operations.

- Regular communication with the vaccine clinic planning team to confirm sites and schedules, adjust messaging accordingly, and update the PCHD website.
- Publish information on the PCHD website and social media for community stakeholders.
- Circulate vaccination location information in the form of flyers and door hangers in collaboration with other partners including community health workers, the area council on aging and PCHD employees working at vaccination sites.
- Share information and documentation regarding the consent process.

Transportation

Pima County will continue to work with rideshare partners and the 2-1-1 Arizona Transportation Hotline in support of the vaccination campaign in Pima County.

- Uber
  - Uber offers free rides in Pima County to vaccination appointments.
  - Passengers must call 855-632-0557 to book transport.
  - Minors must be accompanied by an adult.
  - Parents or guardians must provide car seats or booster seats as needed.
- 2-1-1 Arizona Transportation Hotline
  - Available for health and vaccine transportation needs.
  - Parents or guardians must accompany minors.
  - More information at www.211arizona.org or call 1-855-345-6432

IV. LOGISTICS

Staffing, registration, data collection, reporting, and other operational and logistical aspects will draw upon existing protocols from Pima County's *COVID-19 Accelerated Immunization Plan, Vaccine Equity for Vulnerable Populations in Pima County* and the *COVID-19 Response Point of Dispensing Playbook.* Vaccine will be stored and handled using the CDC's *Vaccine Storage and Handling Toolkit.* Storage and handling information specifically pertaining to Pfizer-BioNTech can be found on the *Pfizer-BioNTech COVID-19 Vaccine Storage and Handling Summary.*

APPENDIX A: Obtaining Consent for Minor COVID-19 Vaccination

On January 21st, 2020, the United States declared the SARS Coronavirus (COVID-19) pandemic as a public health emergency. Over one-year later, COVID-19 continues to pose challenges for our nation and public health. The emergency declaration has expedited the development of vaccines which have been authorized for emergency use by the U.S. Food and Drug Administration (FDA), which includes Pfizer, Moderna, and Johnson and Johnson. COVID-19 vaccination is a safe and effective way to reduce hospitalization and death resulting from infection. Vaccination also protects local and national communities against further spread of COVID-19.

While fatality occurring in young people is rare, the frequency at which youth are experiencing increased severity of symptoms due to variants in COVID-19 is increasing. It is a public health priority to proportionally increase the opportunity to vaccinate youth to counter these effects. Several factors must be considered to vaccinate youth under the age of 18. Pima County Health Department seeks to avoid unnecessary barriers to vaccination while protecting the rights of minors, parents, and guardians and issues the following guidance to its clinics and healthcare providers.

Definitions

- **Authorized adult:** Any adult acting as a Power of Attorney for a minor or a case where another adult may be acting in a legal capacity on behalf of a patient.
- **Consent:** Approval of an individual to perform a service.
- **Emancipated Minor:** Emancipated minors can consent to medical care without parental consent or knowledge. An emancipated minor is individual under 18 who has a court-issued Declaration of Emancipation.
- **Minor:** Any individual legally under the age of 18 is considered a minor.
- **Parent/Guardian:** (from *AZ Immunization Handbook*) The definition of a "parent" is "the natural or adoptive mother or father, a legal guardian appointed by a court, or a "custodian" as defined in A.R.S. 8-201. A parent is a person generally recognized as having care and decision-making responsibility for the child. Providers should use reasonable judgment but may accept as stated by the minor or the adult that the adult is the minor's parent or legal guardian, without requiring formal documentation of that status

Acceptable Consent

The vaccinating agency must go to reasonable lengths to obtain consent from a **parent or guardian** for any **minor** attempting to receive an age-approved vaccination. Forms of acceptable consent include:

- Written consent. Written consent includes a signature from the **parent or guardian** on an appropriate vaccine administration consent form. Written consent may be accepted on a printed or electronic medium.
- Written consent from a **parent or guardian** who is not on site with the **minor**. This can be in the form of a letter written/typed and signed by the **parent or guardian.** The acceptance

of a letter of consent must be documented by the vaccinating agency and the letter should be retained with the patient record.

- Verbal consent provided by a **parent or guardian** who is physically present with the **minor** at the vaccine site. Acceptance of verbal consent must be documented by the vaccinating agency. Documentation of verbal consent should include name, relationship and phone number of the person issuing consent.
- Verbal consent may also be obtained over the phone from a **parent or guardian** if the **minor** is accompanied by another adult as designated by the **parent or guardian.** Acceptance of verbal consent must be documented by the vaccinating agency. Documentation of verbal consent should include name, relationship and phone number of the person issuing consent.

Additional Consent Considerations

- Emancipated minors can consent for themselves if they can provide proof of legal emancipation.
- Any of the above forms of acceptable consent can be given by an **authorized adult.**
- Proof of parent/guardian status will not be routinely requested. However, it can be requested if there are concerns about the safety or wellbeing of the **minor.**
- **Minors** experiencing homelessness can have consent issued by a legal authority responsible for care or organization overseeing care, authorizing consent for reception of an age-approved vaccine. A minor experiencing homelessness can also receive vaccination if reasonable attempts have been made to obtain consent by the vaccinating provider.
- For second doses, if a child attends the same vaccinating site that administered the first dose, signed consent is not required. An official CDC COVID-19 vaccination card documenting administration of a first dose will meet the requirement of obtaining consent. Medical screening should occur at every vaccination visit.
- Providers should use reasonable judgment but may accept as stated by the minor, parent, or guardian that the minor is of age to receive COVID-19 vaccine under the conditions of the FDA Emergency Use Authorization (or FDA Approval) for that vaccine, without requiring formal documentation of birthdate. As of the date of this writing, the Pfizer-BioNTech COVID-19 vaccine is authorized for minors aged 12-17 years; no other COVID-19 vaccine is currently authorized for minors.

Consent and Vaccine Information Documentation

Consent forms should include demographics (name, address, DOB), questions for any medical reasons why NOT vaccinated, place for parent/guardian signature, place to indicate approval to release identifiable information to medical provider, and place for vaccinator to note date and lot number and type of vaccine.

Consent forms should be accompanied by appropriate vaccine information statements (VIS) for fully approved vaccines or FDA Fact Sheet for Recipients and Caregivers for vaccines on an Emergency Use Authorization. All documentation should be provided in multiple languages as needed for patient comfort and comprehension.

Consent forms should be retained with patients records for six (6) years in accordance with Arizona State law.

Managing Emergencies

Defer to Management of Reactions standing order (Appendix C) for management of medical emergencies for minors and adults. In case of adverse reaction in a minor, ensure immediate notification of on-site emergency response and parents or guardians.

APPENDIX B: Sample Consent Form

Pfizer COVID-19 Vaccine

COVID-19 VACCINE INFORMATION AND CONSENT FORM

PIMA COUNTY HEALTH DEPARTMENT

NAME (Last)	(First)	Date of Birth: _____/_____/_____	Age:
ADDRESS			
CITY	STATE	ZIP	DAYTIME PHONE NUMBER
EMERGENCY CONTACT: Name	Relation	Phone Number	

Race: (check only 1)	Ethnicity: (check only 1)	Primary Language:	Gender:
☐ Asian/Polynesian ☐ Black ☐ Multiracial ☐ Native Am/Alaskan ☐ White ☐ Unknown	☐ Not Hispanic ☐ Hispanic ☐ Unknown	☐ English ☐ Other _____	☐ Male ☐ Female ☐ Other

Please answer the health questions below:	Yes	No	Do Not Know
1. Are you feeling sick today?			
2. Have you ever received a dose of COVID-19 vaccine? *If yes, which vaccine product and the date administered: ☐ Pfizer _____ ☐ Moderna _____ ☐ Another Product _____			
3. Have you ever had a severe allergic reaction (e.g., anaphylaxis) to something: For example, a reaction for which you were treated with Epinephrine or EpiPen, or for which you had to go to the hospital?			
*Was the severe reaction after receiving a COVID-19 vaccine?			
*Was the severe reaction after receiving another vaccine or another injectable medication?			
4. Have you received another vaccine in the last 14 days?			
5. Have you received passive antibody therapy (monoclonal antibodies or convalescent serum) as treatment for COVID-19?			
6. Do you have a weakened immune system caused by something such as HIV infection or cancer or do you take immunosuppressive drugs or therapies?			
7. Do you have a bleeding disorder or are you taking a blood thinner ?			
8. Are you pregnant or breastfeeding?			

I have been given a copy and have read the Emergency Use Authorization (EUA) and reviewed the FDA Fact Sheet for Recipients and Caregivers (https://www.fda.gov/media/144414/download) prior to receiving the COVID-19 vaccine. I have had the chance to ask questions that were answered to my satisfaction. I understand the benefits and risks of the vaccine indicated and ask that it be given to me or the person named for whom I am authorized to make this request.

My signature acknowledges that I was advised to remain on site for 15 minutes after receiving the vaccine. Those with previous anaphylactic reactions should stay for 30 minutes.

Date _____ Print Name _____ X _____ Patient or Parent/Guardian Signature

VAX FACT SHEETS

FOR ADMINISTRATIVE USE ONLY

Vaccine	Dose	Route	Date Dose Administered	Vaccine Manufacturer	Lot Number	Expiration Date	Name of Vaccine Administrator
COVID-19	_____ ml ☐ 1st _____ ml ☐ 2nd	☐ IM - L Arm ☐ IM - R Arm					

Vacuna COVID-19 de Pfizer

PIMA COUNTY HEALTH DEPARTMENT

Información y formulario de consentimiento para la vacuna contra Covid-19

APELLIDO	NOMBRE	FECHA DE NACIMIENTO	EDAD:
		_____/_____/_____	

DIRECCIÓN			
CIUDAD	ESTADO	CÓDIGO POSTAL	TELÉFONO DE CONTACTO DURANTE EL DÍA

CONTACTO PARA EMERGENCIAS	Nombre	Parentesco	Teléfono

Raza: (seleccione solo uno)	Grupo étnico: (seleccione solo uno)	Idioma principal:	Sexo:
☐ Asiático o polinesio ☐ Negro ☐ Multirracial ☐ Indígena americano / Alaska ☐ Blanco ☐ No sabe	☐ No hispano ☐ Hispano ☐ No sabe	☐ Inglés ☐ Otro _____	☐ Masculino ☐ Femenino ☐ Otro

Responda a estas preguntas sobre su salud:	Sí	No	No sabe
1. ¿Se siente enfermo hoy?			
2. ¿Ha recibido alguna dosis de la vacuna contra el Covid-19? *Si responde sí, ¿qué vacuna recibió y en qué fecha?: ☐ Pfizer _____ ☐ Moderna _____ ☐ Otra _____			
3. ¿Ha tenido alguna reacción alérgica grave (como anafilaxia); por ejemplo, una reacción que debió ser tratado con epinefrina o una EpiPen, o por la que tuvo que ir al hospital?			
*¿La reacción grave fue después de recibir una vacuna contra el Covid-19?			
*¿La reacción grave fue después de recibir otra vacuna o un medicamento inyectable?			
4. ¿Ha recibido alguna vacuna en los últimos 14 días?			
5. ¿Ha recibido terapia de anticuerpos pasivos (anticuerpos monoclonales o plasma convaleciente) para tratar el Covid-19?			
6. ¿Tiene un sistema inmunitario debilitado por cáncer o por una infección porHIV, toma medicamentos inmunosupresores o recibe terapias inmunosupresoras?			
7. ¿Tiene problemas de coagulación o está tomando algún medicamento anticoagulante?			
8. ¿Está embarazada o amamantando?			

He recibido una copia, leído la Autorización de uso de emergencia (EUA) y he revisado la información de la Hoja informativa para receptores y cuidadores de la FDA (https://www.fda.gov/media/144712/download), antes de recibir la vacuna contra el Covid-19. Pude hacer preguntas que me contestaron a cabalidad. Entiendo los riesgos y beneficios de la vacuna y solicito que me la pongan a mí o la persona para la que estoy autorizado a hacer este pedido.

Con mi firma confirmo que me recomendaron quedarme en el sitio 15 minutos luego de recibir la vacuna. Quienes hayan tenido reacciones alérgicas graves previas deben quedarse 30 minutos.

Fecha	Nombre en letra de imprenta	X Firma del paciente / Padre o tutor

VAX FACT SHEETS

FOR ADMINISTRATIVE USE ONLY (ÁREA EXCLUSIVA PARA USO ADMINISTRATIVO)

Vaccine	Dose	Route	Date Dose Administered	Vaccine Manufacturer	Lot Number	Expiration Date	Name of Vaccine Administrator
COVID-19	_____ ml ☐ 1st _____ ml ☐ 2nd	☐ IM - L Arm ☐ IM - R Arm					

APPENDIX C: Medical Management of Reactions

PIMA COUNTY
HEALTH DEPARTMENT

MEDICAL MANAGEMENT OF REACTIONS IN CHILDREN AND ADULTS

All vaccines or medications have the potential to cause an adverse reaction. In order to minimize adverse reactions, patients should be carefully screened for precautions and contraindications before a vaccine or medication is administered. Even with careful screening, reactions may occur. These reactions can vary from trivial and inconvenient (e.g. soreness, itching) to severe and life threatening (e.g. anaphylaxis). Clinical staff should be familiar with identifying immediate-type allergic reactions, including anaphylaxis, and be competent in treating these events at the time of vaccine or medication administration. Staff should also have a plan in place to contact emergency medical services immediately in the event of a severe reaction. The table below describes procedures to follow if various reactions occur.

REACTION	SYMPTOMS	MANAGEMENT
Localized	Soreness, redness, itching, or swelling at the injection site	Apply a cold compress to the injection site.
	Slight bleeding	Apply an adhesive compress over the injection site.
	Continuous bleeding	Place thick layer of gauze pads over site and maintain direct and firm pressure; raise the bleeding injection site (e.g. arm) above the level of the patient's heart.
Psychological fright and syncope (fainting)	Fright before injection is given	Have patient sit or lie down before vaccination.
	Extreme paleness, sweating, coldness of the hands and feet, nausea, light-headedness, dizziness, weakness, or visual disturbances	Have patient lie flat or sit with head between knees for several minutes. Loosen any tight clothing and maintain an open airway. Apply cool, damp clots to patient's face and neck.
	Fall, without loss of consciousness	Examine the patient to determine if injury is present before attempting to move the patient. Place patient flat on back with feet elevated.
	Loss of consciousness	Check the patient to determine if injury is present before attempting to move the patient. Place patient flat on back with feet elevated. Call 911 if patient does not recover immediately.
Anaphylaxis	Sudden or gradual onset of generalized itching, erythema (redness), or urticaria (hives); angioedema (swelling of the lips, face, or throat); severe bronchospasm (wheezing); shortness of breath; shock; abdominal cramping; or cardiovascular collapse.	See "Emergency Medical Protocol for Management of Anaphylactic Reactions in Children and Adults" on the next page for detailed steps to follow in treating anaphylaxis.

Emergency Medical Protocol for Management of Anaphylactic Reactions in Children and Adults

1. If itching and swelling are confined to the injection site where the vaccination was given, observe patient closely for the development of generalized symptoms.

2. If symptoms are generalized, stay with the client, yell for help, and instruct the first responder to **CALL 911** and get the automated external defibrillator (AED). The primary healthcare professional assesses the airway, breathing, circulation, and level of consciousness of the patient. Vital signs should be monitored continuously.

3. **First-Line Medication Treatment: The first-line and most important therapy in anaphylaxis is epinephrine. There are NO contraindications to epinephrine in the setting of anaphylaxis.**

   Aqueous Epinephrine 1:1000 dilution (1mg/1mL) is available in ampules, vials of solution, or prefilled syringes, including epinephrine auto injectors (e.g., EpiPen, EpiPen Jr., Auvi-Q). * If auto injectors are stocked, at least three should be available (in both pediatric and adult formulations).

   a. **CHILDREN:** Administer aqueous epinephrine 1:1000 dilution (i.e. 1 mg/mL) intramuscularly. Epinephrine should be given in the vastus lateralis muscle, and can be injected through clothing if necessary. The standard dose is 0.01 mg/kg body weight, up to 0.5 mg maximum single dose in children and adolescents. * See dosing charts on page 3.

   b. **ADULTS:** Administer aqueous epinephrine 1:1000 dilution intramuscularly. Epinephrine should be given in the vastus lateralis muscle, and can be injected through clothing if necessary. The standard dose is 0.01 mg/kg body weight. The adult dose ranges from 0.3mL to 0.5mL, with maximum single dose of 0.5 mL.

4. Monitor the patient closely until EMS arrives. Perform cardiopulmonary resuscitation (CPR), if necessary, and maintain airway. Keep patient in supine position (flat on back) unless he or she is having breathing difficulty. If breathing is difficult, patient's head may be elevated, provided blood pressure is adequate to prevent loss of consciousness. If blood pressure is low, elevate legs. Monitor blood pressure and pulse every 5 minutes.

5. If EMS has not arrived and symptoms are still present, repeat dose of epinephrine every 5-15 minutes for up to 3 doses, depending on patient's response.

6. Record the patient's reaction (e.g. hives, anaphylaxis) to the vaccine or medication, all vital signs, medications administered to the patient, including the time, dosage, response, and the name of the medical personnel who administered the medication, and other relevant clinical information. If the reaction is due to a vaccine, report the incident to the Vaccine Adverse Event Reporting System (VAERS).

				Epinephrine Dose	
	Age Group	**Range of weight (lb)**	**Range of weight (kg)**	**1mg/mL injectable (1:1000 dilution); intramuscular Minimum dose: 0.05 mL**	**Epinephrine auto injector, 0.15 mg or 0.3**
Infants and Children	1-6 months	9-19 lbs	4-8.5 kg	0.05 mL (or mg)	Off label
	7-36 months	20-32 lbs	9-14.5 kg	0.1 mL (or mg)	Off Label
	37-59 months	33-39 lbs	15-17.5 kg	0.15 mL (or mg)	0.15 mg/dose
	5-7 years	40-56 lbs	18-25.5 kg	0.2- 0.25 mL (or mg)	0.15 mg/dose
	8-10 years	57-76 lbs	26-34.5 kg	0.25 – 0.3 mL (or mg)	0.15 mg or 0.3 mg/dose
Teens	11-12 years	77-99 lbs	35-45 kg	0.35 – 0.4 mL (or mg)	0.3 mg/dose
	13 years & older	100+ lbs	46+ kg	0.5mL (or mg) – max. dose	0.3 mg/dose

*** **NOTE:** If body weight is known, then dosing by weight is preferred. If weight is not known or not readily available, dosing by age is appropriate.

This policy and procedure shall remain in effect for all patients of the Pima County Health Department until rescinded or until one year after review.

Jill Weinstein DNP, FNP-C — July 28, 2021

Jill Weinstein, Clinician DNP, FNP-C **Date**

Revised July 2021

APPENDIX D: Pediatric COVID-19 Vaccination Operational Planning Guide

Pediatric COVID-19 Vaccination Operational Planning Guide

Overview

Multiple vaccine manufacturers are currently developing COVID-19 vaccines for children younger than 12 years old. This Operational Planning Guide outlines key aspects of a COVID-19 vaccination program for children younger than 12 years old and was designed to inform jurisdictional planning under the assumption of FDA authorization and CDC recommendations of at least one COVID-19 vaccine product for children of this age. An Emergency Use Authorization (EUA) application for the Pfizer-BioNTech vaccine for children 5-11 years old has been submitted to the FDA and may receive authorization before other vaccines. Therefore, this guidance will include details about the anticipated Pfizer-BioNTech product and may be updated as other manufacturers submit applications for FDA review. While some details about the pediatric COVID-19 vaccination program are still pending, this guide aims to inform planning based on current facts and planning assumptions and introduces strategies for consideration. Given jurisdictions' extensive experience implementing a COVID-19 vaccination program for adults and adolescents, this guide will mainly focus on key differences between that program and one designed to vaccinate children younger than 12 years old. Additional information will be released as it becomes available.

FACTS

- There are approximately 28 million children between the ages of 5-11 years old in the United States. The U.S. government has procured enough vaccine to support vaccination of this population.
- The Pfizer-BioNTech vaccine for 5–11-year-olds will be a new product configuration with new packaging, new preparation, and a new national drug code (NDC). The current product for adults and adolescents should not be used in children.
- The packaging configuration will be 10-dose vials in cartons of 10 vials each (100 doses total) pending FDA authorization. The product will be delivered in a newly updated product shipper at -80°C. Once the product arrives at the provider site, it can be stored for up to 10 weeks at 2 to 8°C and 6 months at ultracold temperatures of -90 to -60°C.
- Based on information current as of October 14th, it is anticipated that once a vial is opened, doses must be used within 6 hours.
- COVID-19 pediatric vaccines will require diluent. The diluent will be provided with ancillary supplies which are configured specifically for use in children. NOTE – reconstitution of the product for use on 5–11-year-olds uses a different volume of diluent than the adult formulation.
- The new NDC will require additional coding and information technology accommodations, which are underway.
- The PREP Act and the PREP Act Declaration issued by the Secretary of the Department of Health and Human Services authorize and provide liability protections to licensed providers and others identified in the declaration to administer COVID-19 vaccines authorized by FDA, including COVID-19 vaccines authorized for administration to

children. This authorization preempts state requirements that would otherwise prohibit, or effectively prohibit, the providers from administering the vaccine. The PREP Act Declaration authorizes certain providers listed in the Declaration to administer vaccines regardless of state requirements. For example, the Declaration authorizes pharmacists, pharmacy interns and pharmacy technicians nationwide to order and/or administer COVID-19, influenza vaccines, and other vaccines authorized by FDA and recommended by CDC for children ≥3 years old (Please see: https://www.hhs.gov/sites/default/files/prep-act-guidance.pdf)

- The months of November and December have multiple holidays. This should be considered in site selection and planning

ASSUMPTIONS

- FDA's Vaccines and Related Biological Products Advisory Committee (VRBPAC) is scheduled to meet on October 26th. The CDC's Advisory Committee on Immunization Practices (ACIP) is scheduled to meet on November 2nd and 3rd, 2021. Jurisdictions should be ready to vaccinate children 5–11 years old shortly thereafter, pending FDA authorization and CDC recommendations.
- To ensure efficient rollout of vaccine supply, jurisdictions should plan their ordering strategy now and identify the priority locations and sequence of activating these priority locations during the initial weeks of the pediatric vaccination efforts.
- Shipment for pediatric vaccines can begin once FDA issues the EUA, and vaccine administration can begin once the CDC Director makes a recommendation.
    - For the initial roll out, a large, one-time bolus of pediatric product will be made available pro-rata for jurisdictions to pre-order.
        - Pre-orders will occur in three waves beginning October 20th. Jurisdictions will have 48 hours to enter orders for each wave.
        - Wave 1: Order cap will be raised October 20th
        - Wave 2: Order cap will be raised again on October 22nd
        - Wave 3: Order cap will be raised again on October 24th. This will be the final order cap raise of the initial launch period, and standard order cap cycles will begin the first full week of the launch.
        - Pre-ordering through these waves will allow for a manageable and equitable launch for this new vaccine
    - This bolus of supply will ensure that vaccine can be placed in many locations nationwide, making it easier for children to get vaccinated. These doses will remain in ordering caps for jurisdictions to order as needed. Second dose planning is the responsibility of the jurisdiction and should be considered as part of the initial order.
    - Depending on the jurisdiction's roll-out plan, the entire allocation may not need to be ordered the first week. Any unordered doses will remain allocated to the jurisdictions to order in the future as needed.
    - After this initial bolus, a weekly supply will be made available to help sustain the network and support site specific needs as vaccine is administered.

  - Jurisdictions and providers should continue to manage sites' second dose needs through supply provided. There is no separate allocation for second doses.
  - The minimum order will be 300 doses for program launch and 100 doses in subsequent weeks. Jurisdictions should account for these minimum order quantities when identifying the initial sequence of provider site activation for receipt of pediatric COVID-19 vaccine.
- Not all COVID-19 vaccination sites will need to receive pediatric vaccines. Vaccination providers that are most likely to vaccinate pediatric populations should be prioritized, with provider types likely varying across communities (e.g., pediatric clinics, federally qualified health centers [FQHC], pharmacies, rural health clinics [RHC]).
- Pharmacies participating in the Federal Retail Pharmacy Program (FRPP) will be able to order vaccine to select pharmacy locations, increasing the number of locations children may go to get vaccinated.
- Pharmacies will be asked to select locations within their network that can best manage supply and that are ready to administer vaccine to pediatric populations.
- Most jurisdictions have enrolled the majority of Vaccines for Children (VFC) providers as COVID-19 vaccination providers.
- Dashboards will be developed within the Tiberius application that will allow jurisdictions the ability to see their order thresholds and optimally prioritize providers to receive initial shipments.
- The public will be directed to use www.vaccines.gov to help find providers offering COVID-19 pediatric vaccines. Thus, it is critical that all providers report pediatric vaccine supply to VaccineFinder so that their location may be displayed on www.vaccines.gov.
- The U.S. government and the manufacturer will be providing additional training to prepare providers to administer vaccine to younger children; providers and locations will all need to be trained.
- To support increased logistics needed to push out large number of pediatric doses during the first week, no orders for Pfizer adult vaccine shipments (1170 product configuration) will be distributed during the pediatric product launch. This will be temporary and last for the first few days (exact dates to be determined based on timing of FDA authorization).

PROJECTED LAUNCH PLAN – CONSIDERATIONS FOR JURISDICTIONS

To enhance readiness to launch the pediatric COVID-19 vaccination program and begin administering vaccine to children immediately following the FDA authorization and CDC recommendations, jurisdictions should identify providers that will receive the doses of pediatric vaccine in weeks one and two of program launch.

Similar to other COVID-19 program launches (adolescents, additional doses, booster), the first weeks of launch will likely require sites to be ready to vaccinate a larger volume of children who may present once the program launches. The public will be directed to use www.vaccines.gov to help people find providers offering pediatric vaccine. Jurisdictions will need to determine the sites to receive initial supplies of vaccine, balancing making vaccine accessible to all, especially

where vaccine demand is expected to be high, while avoiding distributing inventory across too many sites and risking wastage. The goal is to allow for the most equitable access and efficient reach of the target pediatric age groups in these initial weeks when demand is higher.

Considerations for week 1 include:

- Clinic location and access to population (population density, rural access, access in communities that may be disproportionally impacted by COVID-19)
- Ability to handle 300 dose product configurations or has plans in place for redistribution
- Vaccination capacity/throughput to meet community demand
- Once open, doses in vials should be used within 6 hours. Clinics should consider vial size (10-doses) and 6-hour timeframe when scheduling children for vaccination, especially early in the program to minimize waste and optimize use of supply.
- Sites understand the U.S. Government will not offer second dose management of vaccine in ordering processes. Sites should manage their inventory to assure availability of second doses in their supply chain. Keep in mind, those receiving vaccine shortly after EUA may schedule second doses during November holidays.
- Overall site readiness (staffing, training, scheduling capabilities)

Considerations following initial rollout include:

- Ability to handle at least 100 dose product configurations or has plans in place for redistribution.
- Sites ordering more than 100 doses will find 10 packs consolidated into single shippers
- All other criteria same as week 1

PEDIATRIC READINESS CHECKLIST	
Main Theme	**Key activities for readiness and response**
Supply and Ordering Readiness	❑ Review CDC and manufacturer materials regarding product configuration, shipping, storage, dosing, intervals, and adverse event profiles as they become available. ❑ Determine which provider locations will receive initial vaccine supply, balancing equitable access with vaccinating capacity and consideration of initial demand. Also ensure that an expanded set of providers will be able to provide equitable and convenient access to all children. Consider November holidays when selecting initial sites as second doses may be due during a holiday week. ❑ A list of providers, and sequence of provider activation, for the first week of vaccine deliveries should be finalized on the week of Oct 19th. CDC will be requesting information on initial sites early to facilitate validation and delivery of initial orders.

	❑ Be ready to submit pre-orders beginning October 20th.
	❑ Continue to optimally use vaccine supply.
	  ❑ Order additional supply responsibly to avoid accumulation of unadministered inventory.
	  ❑ Understand vaccine wastage, and while seeking to minimize vaccine loss, ensure that no vaccination opportunity is missed.
	❑ Continue to manage and accurately report on-hand product inventory to track near-expiry and redistribution.
	❑ Track trends in vaccine administration and adjust ordering patterns accordingly.

Provider Readiness	❑ Enrolling an adequate network of providers:
	  ❑ Review the adequacy of the provider network to ensure equitable access across all pediatric populations.
	  ❑ Facilitate enrollment of VFC providers who can become COVID-19 vaccination providers, with a focus on promoting equitable access by filling a geographic gap in communities that are disproportionally impacted by COVID-19, particularly those with a high social vulnerability index.
	  ❑ Reach out to tribal nations within the respective areas for involvement in planning efforts.
	  ❑ Consider offering school-located vaccination clinics, especially in areas with limited access to providers (e.g., rural or frontier areas).
	  ❑ Review CDC's Considerations for Planning School-Located Vaccination Clinics.
	  ❑ Consider identifying schools or school districts that routinely provide school-located influenza vaccination or that were successful in providing COVID-19 vaccination to adolescents and consider implementing those clinics for 5–11-year-old children.
	  ❑ Identify and facilitate enrollment of providers who frequently care for children with disabilities or special healthcare needs (e.g., children's hospitals, pediatric subspecialty clinics).

	❑ Consider that November and December have multiple holidays when selecting sites. ❑ Preparing enrolled providers to receive pediatric COVID-19 vaccine: ❑ Develop a plan to identify when additional sites may be needed to increase vaccination capacity of 5-11-year-olds especially during the initial weeks of the vaccine program or when community level willingness to get vaccinated is high. ❑ Disseminate training and communication materials to providers. ❑ Remind enrolled providers to make immunization information system changes as needed to allow for pediatric populations. ❑ Remind enrolled providers to prepare scheduling systems and bolster capacity for call center and website as needed to handle additional volume. ❑ Ensure providers or other on-location staff are equipped and trained to respond to possible severe allergic reactions like anaphylaxis. ❑ Ensure providers are prepared to co-administer COVID-19, influenza, and other childhood vaccines, when appropriate. ❑ Encourage providers to consider offering COVID-19, influenza, or other routine vaccines, as feasible, to additional eligible persons (e.g., siblings, family members, community members). ❑ Reinforce that providers are required to report certain adverse events following COVID-19 vaccination to the Vaccine Adverse Event Reporting System (VAERS) and support providers in encouraging parents or guardians to enroll their children in v-safe. ❑ Routinely evaluate the adequacy of the provider network, identifying gaps and whether additional vaccination locations (e.g., pharmacies, school-located and other temporary vaccination clinics, FQHCs, rural health clinics) may be needed to further increase equitable access and ensure vaccine equity. ❑ To help ensure equitable access, pharmacy locations selected should include those that help fill geographic gaps in vaccine providers or will be open during holidays

APPENDIX E: Pfizer-BioNTech COVID-19 Vaccine One Pager

Pfizer-BioNTech COVID-19 Vaccines

PRELIMINARY – SUBJECT TO CHANGE PENDING REGULATORY GUIDANCE AND AUTHORIZATION/APPROVAL

Description	Current Adult/Adolescent Formulation (1170 and 450 packs)	Future Pediatric Formulation
	Dilute Prior to Use	*Dilute Prior to Use*
Age Group	12 years and older	5 to <12 years**
Vial Cap Color	PURPLE 	ORANGE 
Dose	30 mcg	10 mcg
Injection Volume	0.3 mL	0.2 mL
Fill Volume (before dilution)	0.45 mL	1.3 mL
Amount of Diluent* Needed per Vial	1.8 mL	1.3 mL
Doses per Vial	6 doses per vial (after dilution)	10 doses per vial (after dilution)
Storage Conditions		
ULT Freezer (-90°C to -60°C)	9 months	6 months
Freezer (-25°C to -15°C)	2 weeks	N/A
Refrigerator (2°C to 8°C)	1 month	10 weeks

Q: Can the current adult/adolescent formulation (purple cap) be used to vaccinate children 5 to <12 years old once the vaccine is authorized for this age group?

A: No. For children under 12 years of age, you cannot use the current formulation and will need to use the future pediatric (orange cap) formulation.

Purple Cap – Adult/Adolescent: Authorized only for aged 12 years and older

Orange Cap – Pediatric: Future authorization for aged 5- to 12 years. A separate vaccine formulation specific for a 10mcg dose will be introduced.

***NOTE:** Use of the current adult/adolescent formulation (purple cap) to prepare doses for children 5 to <12 years would result in an injection volume for the 10mcg dose of 0.1mL, which is both generally considered too small for typical IM injections and has not been studied.*

**Diluent: 0.9% sterile Sodium Chloride Injection, USP (non-bacteriostatic; DO NOT USE OTHER DILUENTS*

***The vaccine is currently under emergency use authorization review by the Food and Drug Administration (FDA) for children 5 to <12 years old*

10/7/2021