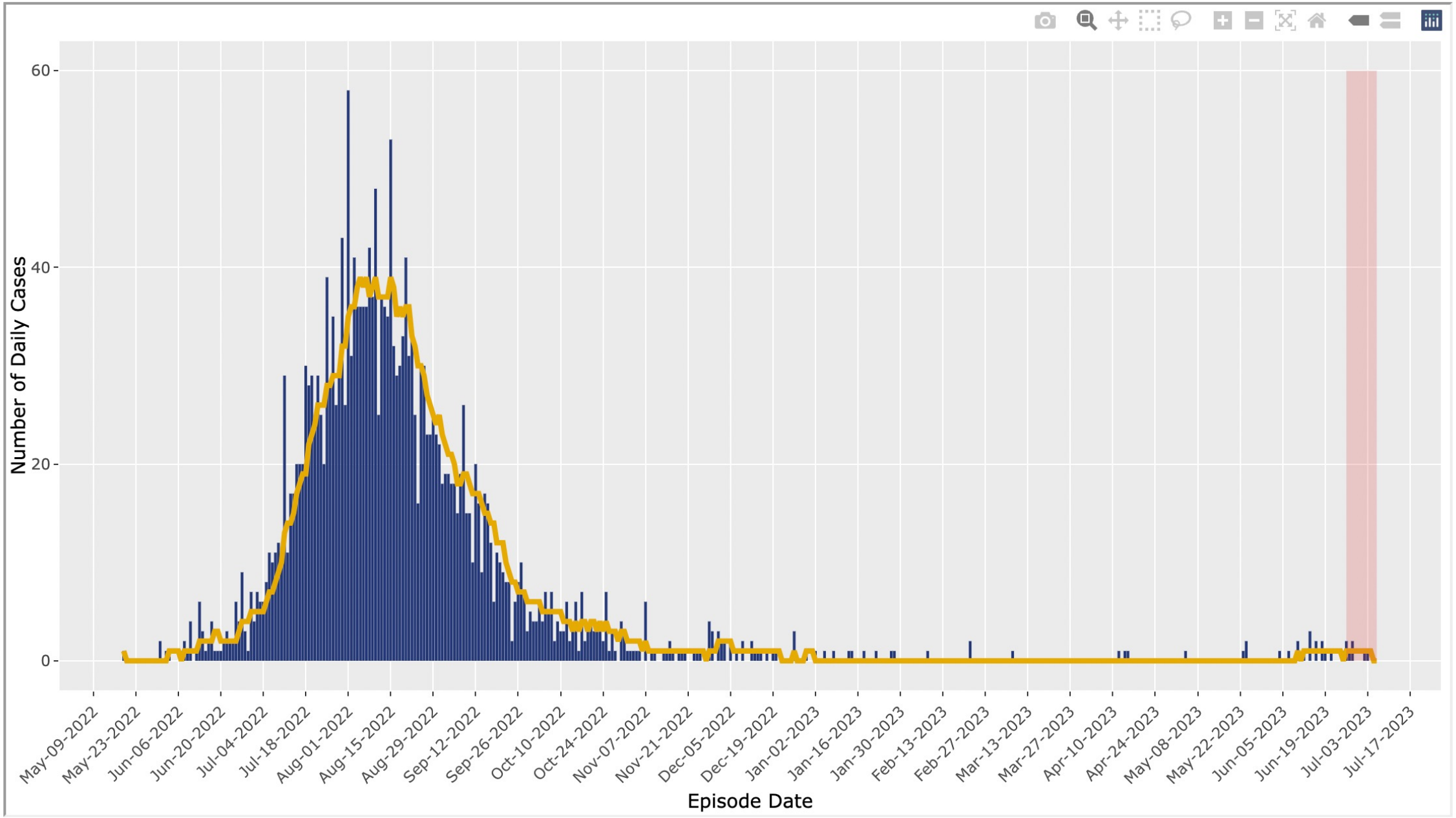
Mpox Update

CASE[1] COUNTS BY EPISODE DATE



Episode date is defined as the earliest existing value of: Date of Onset, Date of Diagnosis, Date of Death, Date Received, Specimen Collection Date.

The JYNNEOS vaccine for mpox

Anyone who requests vaccination can receive it without having to disclose any information on personal risk.

Groups at highest risk for contracting mpox include:

- Any man or transgender person who has sex with men or transgender persons
- Persons of any gender or sexual orientation who engage in commercial sex work
- Persons living with HIV
- Persons who had skin-to-skin or intimate contact with someone with suspected or confirmed mpox
- Sexual partners of people in any of the above groups
- People who anticipate being in any of the above groups

Residents seeking the JYNNEOS vaccine can get it from their healthcare provider or visit myturn.ca.gov

Mpox Vaccination Efforts To Date

As of 07/16/23

Mpox Vaccinations Administered

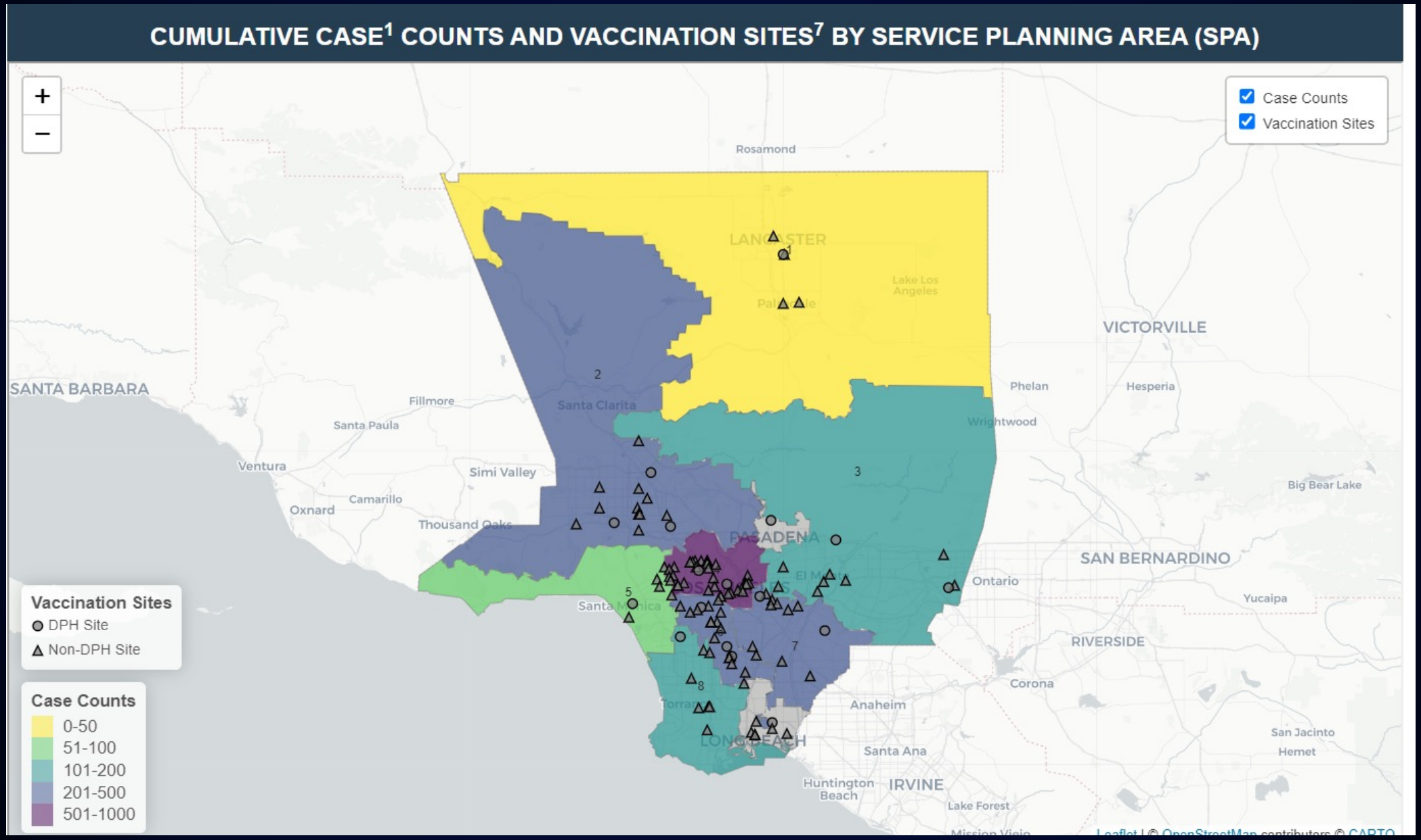
Total Doses Administered

123,113 Doses

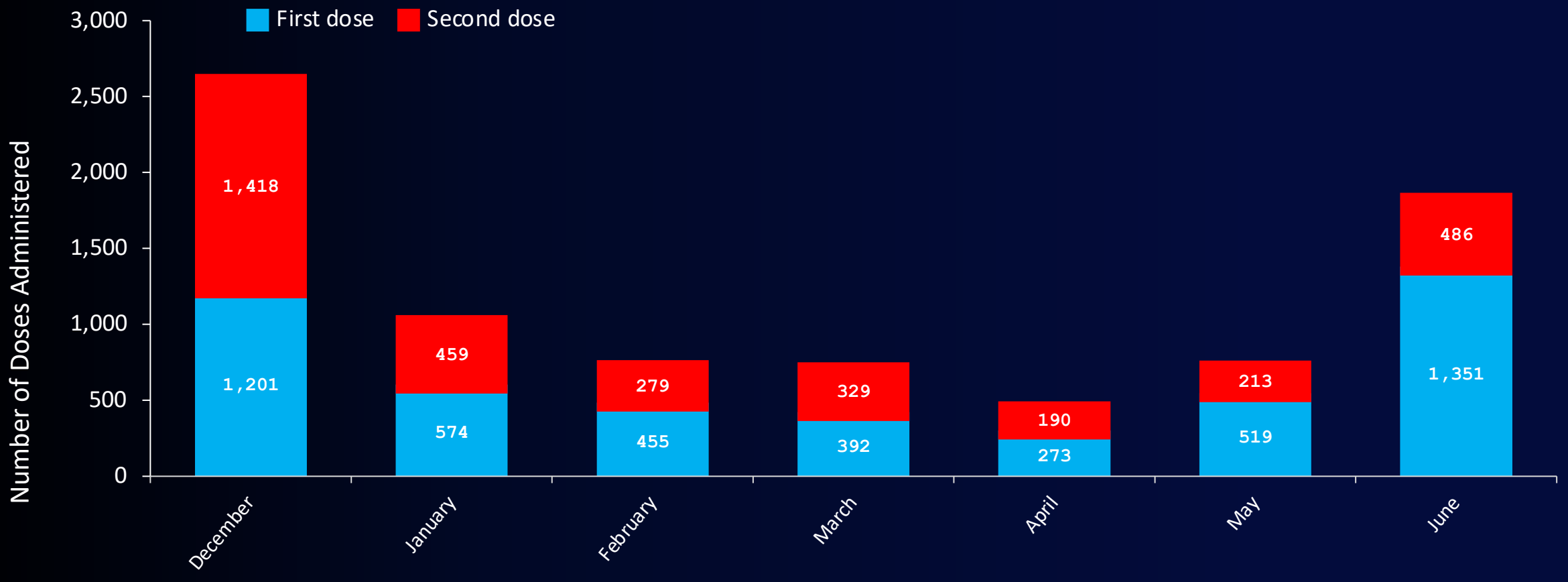
Vaccination Status

- Persons Vaccinated with At Least One Dose: 75,826
- Persons Vaccinated with Two Doses: 47,064
- Percent of Eligible Individuals with a Second Dose: 62.6%

Mpox Vaccination Sites in LA County (N=122) Data as of July 14, 2023

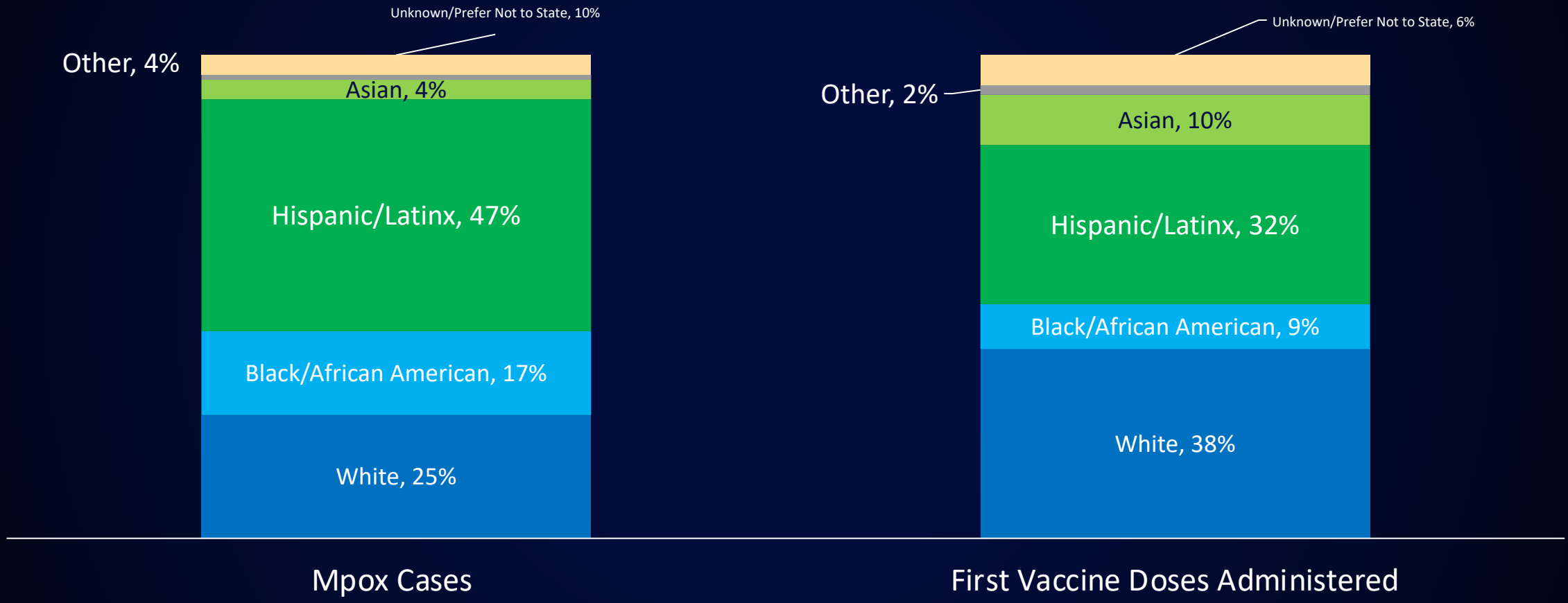


Total JYNNEOS Doses Administered, by First and Second Doses, by Month



*last data point is only partial (until data is available for the whole month)

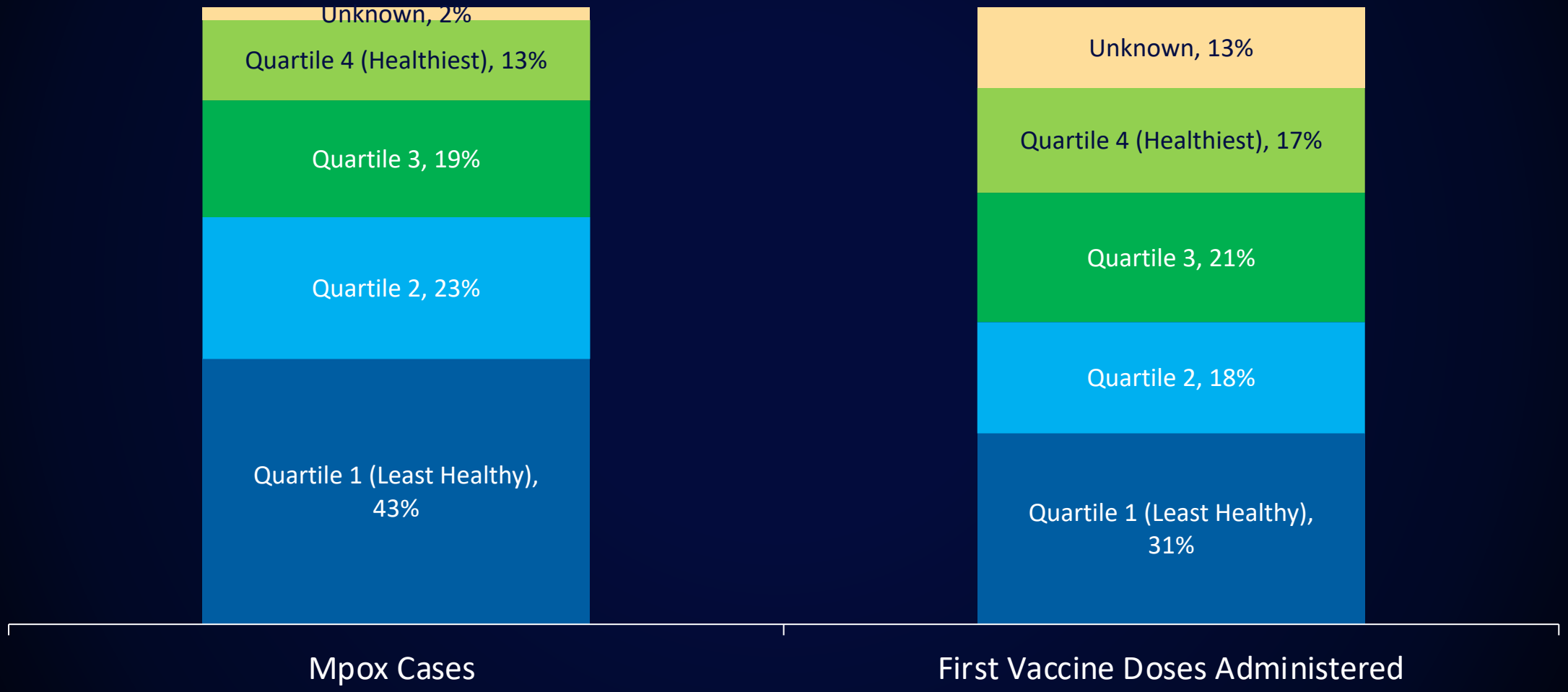
Race/Ethnicity of Mpox Cases vs. First Vaccine Doses, Data As of 6/22/23



Note: The "'Other" category includes: American Indian or Alaska Native, Native Hawaiian or Other Pacific Islander, Multiple Race, and Other.

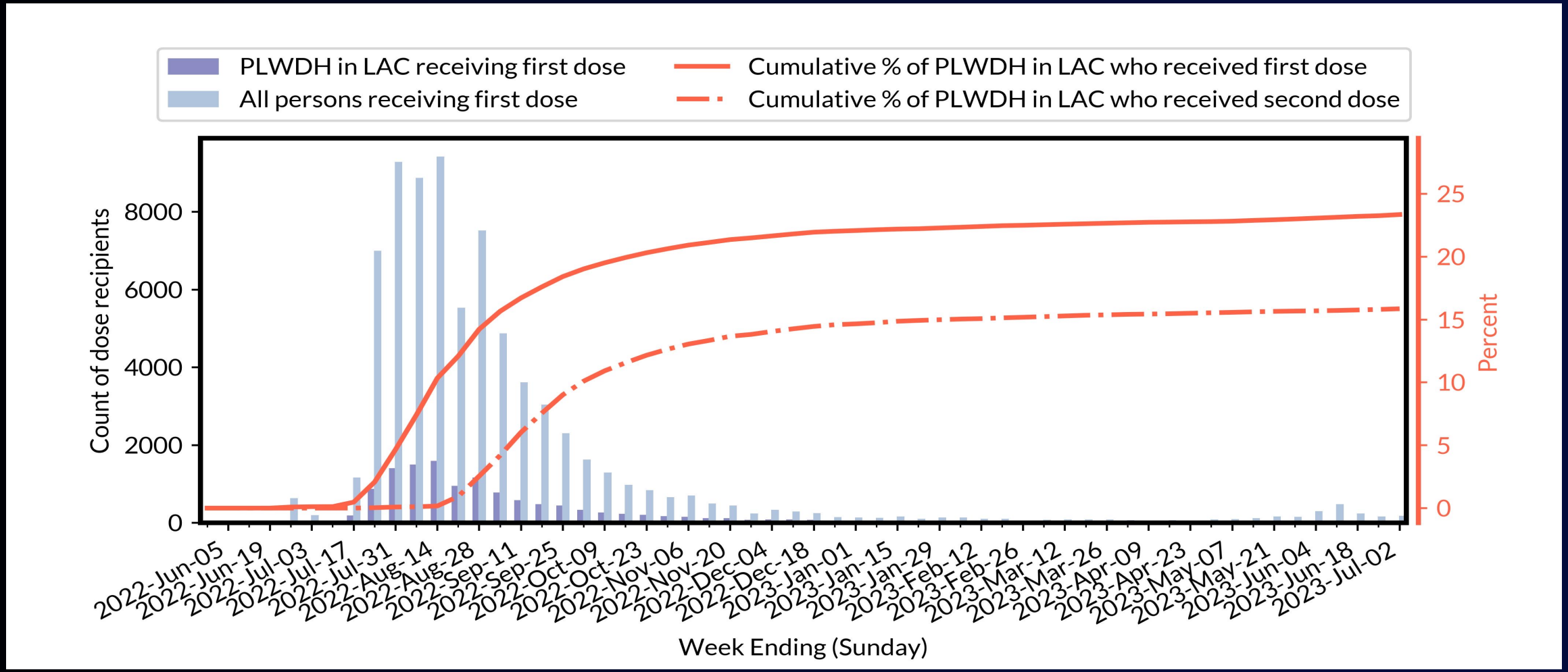
For more information on mpox, visit:
ph.lacounty.gov/Monkeypox/

HPI Quartile for Mpox Cases vs. First Vaccine Doses, Data As of 6/22/23

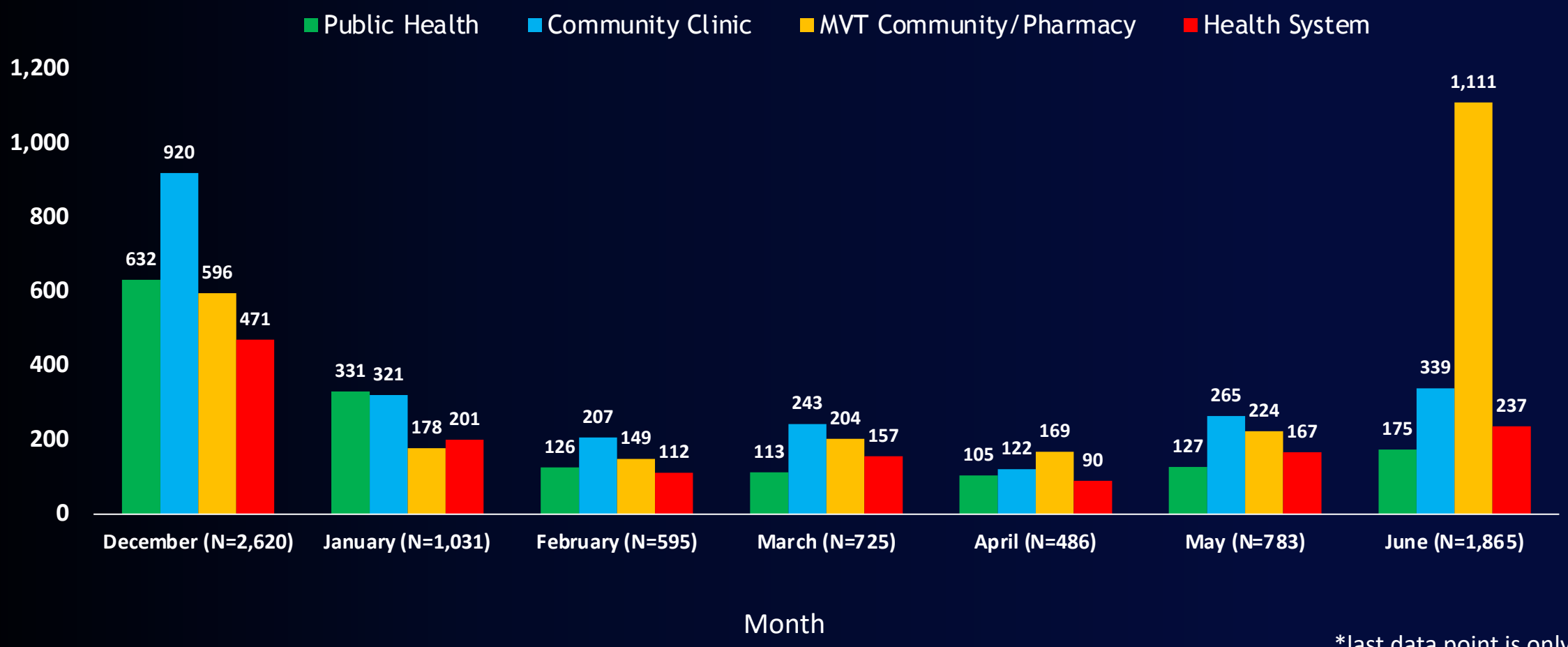


JYNNEOS Vaccination Among Persons Living with Diagnosed HIV, By Week

Week Ending May 29, 2022 through Week Ending July 7, 2023



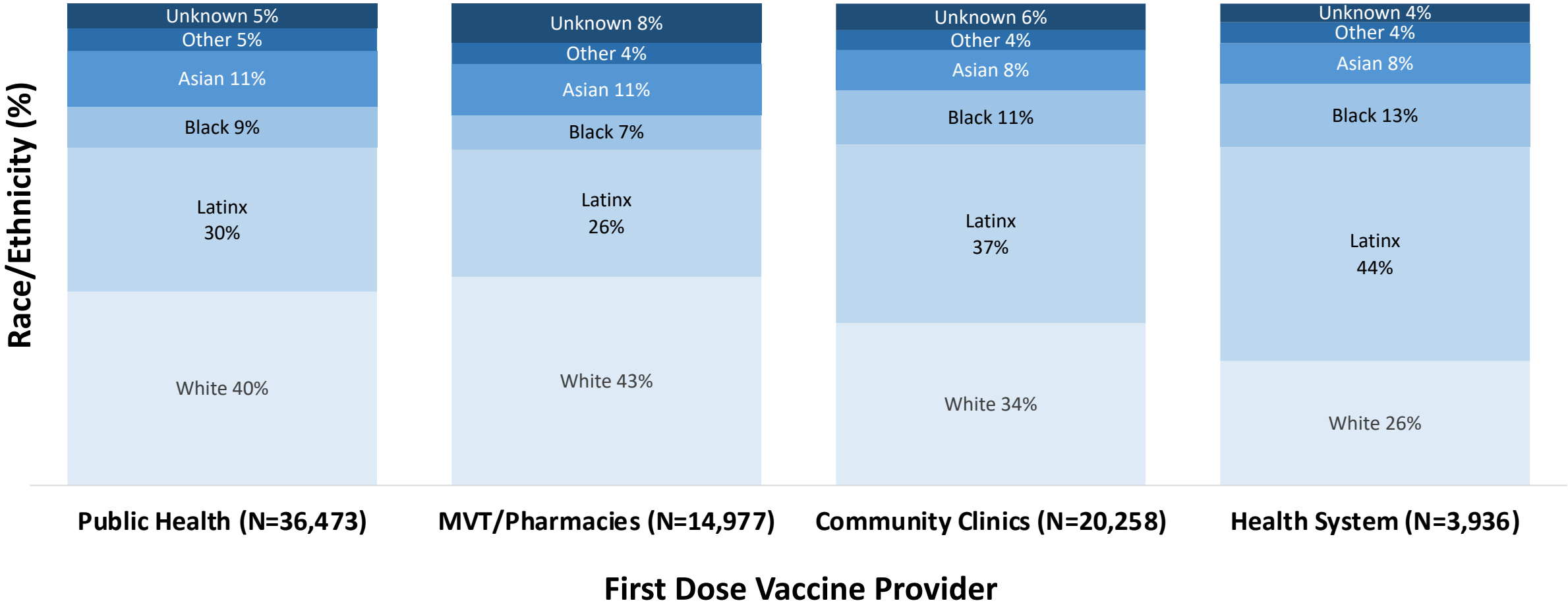
Number of JYNNEOS Vaccine Administrations, By Vaccine Provider and Month



Excludes sites with missing provider information

*last data point is only partial (until data is available for the whole month)

Distribution of Race/Ethnicity Among Persons Receiving 1+ Doses of JYNNEOS By 1st Dose Provider, Los Angeles County, May 27, 2022 through July 9, 2023 (N=75,644*)



*Excludes 61 persons with missing first dose provider information. Other Race includes American Indian or Alaska Native, Native Hawaiian or Other Pacific Islander, or persons reporting Other race. Unknown race Includes persons who reported they preferred not to state their race/ethnicity and other persons with unknown race/ethnicity.

Nirsevimab

nouncements

FDA NEWS RELEASE

FDA Approves New Drug to Prevent RSV in Babies and Toddlers

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For Immediate Release: July 17, 2023

Today, the U.S. Food and Drug Administration approved Beyfortus (nirsevimab-alip) for the prevention of Respiratory Syncytial Virus (RSV) lower respiratory tract disease in neonates and infants born during or entering their first RSV season, and in children up to 24 months of age who remain vulnerable to severe RSV disease through their second RSV season.

Nirsevimab

- Monoclonal antibody directed against the prefusion conformation of the RSV fusion (F) protein
  - Not a vaccine and is being regulated as a drug.
- Proposed indication--prevention of RSV lower respiratory tract disease in:
  - Neonates and infants born during or entering their first RSV season
  - Children up to 24 months of age who remain vulnerable to severe RSV disease through their second RSV season
  - Proprietary name: Beyfortus (conditionally granted)

Trial 03: Premature infants (29-35 weeks GA)

- Randomized subjects (N=1453)
  - 52% Male
  - 72% White, 18% Black or African American
  - 20% of subjects from US
  - 68% from Northern Hemisphere
- Mean Age 3.3 months
- Mean Weight 4.6kg
- 98% subjects were younge than 8 month of age

Trial 03: Incidence of MA-RSV-LRTI Through Day 150 Postdose

Primary Analysis Results Trial 03

	Nirsevimab N=969	Placebo N=484
Events (# of subjects, n (%))	25 (2.6)	46 (9.5)
Subjects requiring imputation* n (%)	24 (2.5)	11 (2.3)
RRR‡ (95% CI) §	70.1% (52.3% to 81.2%) p < 0.0001	

*Subjects with missing outcomes through Day 150 postdose. The final status of those subjects was imputed based on the observed placebo rate conditional on stratification factors using multiple imputation approach.
‡RRR: relative risk reduction
§ Poisson regression model with robust variance with of treatment group and age group at randomization and dichotomous temperate hemispheres as covariates; CI: confidence interval

https://www.fda.gov/media/169322/download

Trial 04: Full term infants

- Randomized subjects (N= 1490)
- ≥35 weeks of gestation*
- 52% Male
- 53% White, 29% Black or African American
- 29% of subjects from US
- 69% from Northern Hemisphere
- Mean Age 2.9 months
- Mean Weight 5.5 kg
- 97% of subjects younger than 8 months of age

Trial 04: Incidence of MA-RSV-LRTI Through Day 150 Postdose

Primary Analysis Results Trial 04 (Primary Cohort)

	Nirsevimab N=994	Placebo N=496
Events (# of subjects, n (%))	12(1.2)	25(5.0)
Subjects requiring imputation* n (%)	16(1.6)	7(1.4)
RRR‡ (95% CI)	74.9% (50.6% to 87.3%) p < 0.0001	

*Subjects with missing outcomes on Day 150 postdose. The final status of those subjects was imputed based on the observed placebo rate conditional on stratification factors using multiple imputation approach.
‡RRR: relative risk reduction
§ Poisson regression model with robust variance with of treatment group and age group at randomization as covariates; CI: confidence interval

https://www.fda.gov/media/169322/download

Proposed indication by Sanofi

Nirsevimab Implementation

		
Protect infants born…	**Before the RSV season (April – October)**	**During the RSV season (November – March)**
When?	**At beginning of season**	**At birth before discharge**
Where?	**In office, during existing well visit before start of season**	**In hospital**
How?	**Intramuscular injection with pre-filled syringe (stored at 2-8°C)**	

Simple, vaccine-like implementation provides protection to all infants throughout the RSV season

https://www.fda.gov/media/169323/download

FDA advisory committee vote:

- Antimicrobial Drugs Advisory Committee (AMDAC) voted unanimously 21 to 0 that nirsevimab has a favorable benefit risk profile
- 19 to 2 in support of nirsevimab's favorable benefit risk profile for children up to 24 months of age who remain vulnerable to severe RSV disease through their second RSV season.
- FDA approved July 17th
- Next step: Meeting of Advisory Committee on Immunization Practices—August 3rd
  - VFC resolution

Draft - July 17, 2023

MEETING OF THE ADVISORY COMMITTEE ON IMMUNIZATION PRACTICES (ACIP)
Centers for Disease Control and Prevention
Atlanta, Georgia 30329
August 3, 2023

Thursday, August 3, 2023

	AGENDA ITEM	PRESIDER/PRESENTER(s)
11:00	**Welcome and introductions**	Dr. Grace Lee (ACIP Chair) Dr. Melinda Wharton (ACIP Executive Secretary, CDC)
11:15	**Respiratory Syncytial Virus Vaccines - Maternal/Pediatric**	
	Introduction	Dr. Sarah Long (ACIP, WG Chair)
	Nirsevimab: proposed recommendation, updated nirsevimab EtR, and clinical considerations	Dr. Jefferson Jones (CDC/NCIRD)
	EtR summary	Dr. Jefferson Jones (CDC/NCIRD)
	Feasibility / implementation / plans for monitoring safety/effectiveness	Dr. Georgina Peacock (CDC/NCIRD)
	2nd season(update on risk factors for severe disease)	Dr. Jefferson Jones (CDC/NCIRD)
	Clinical considerations	Dr. Jefferson Jones (CDC/NCIRD)
	Workgroup considerations / proposed recommendations	Dr. Jefferson Jones (CDC/NCIRD)
1:25	**Vaccines for Children Resolution**	Dr. Jeanne Santoli (CDC/NCIRD)
1:40	***Break***	