



# NYC Health Care Coalition (NYCHCC) Leadership Council Meeting co-hosted with the Staten Island Community Organizations Active in Disaster (COAD)

NYC DOHMH OFFICE OF EMERGENCY PREPAREDNESS AND RESPONSE  
BUREAU OF HEALTHCARE AND COMMUNITY READINESS

Thursday, December 9, 2021



Welcome!



# Agenda

▶ **2:00 – 2:05 PM: Arrivals / Opening Remarks and Welcome**

- **Marsha Williams**, Senior Director, Healthcare System Readiness, OEPR-Bureau of Healthcare and Community Readiness, NYC DOHMH
- **Frank Blancero**, Program Director, Staten Island Not For Profit Association, Staten Island Community Organizations Active in Disaster (SI COAD)

▶ **2:05 – 2:13 PM: Growing as a Borough Coalition Through Maintenance, Evaluation, and Expansion**

- **Frank Blancero**, Program Director, Staten Island Not For Profit Association, Staten Island Community Organizations Active in Disaster (SI COAD)

▶ **2:13 – 2:21 PM: Monoclonal Antibody Program at Richmond University Medical Center**

- **Johnathon LeBaron**, Chairman of Emergency Medicine, Richmond University Medical Center

▶ **2:21 – 2:27 PM: Developmental Disabilities: Providers Response to the COVID-19 Pandemic**

- **cRis marchionNe**, Executive Director, Person Centered Care Services

▶ **2:27 – 2:33 PM: Vaccine Access, Hesitancy, and Equity in the Community**

- **Frank Morisano**, Senior Director, Community Health, Staten Island University Hospital-Northwell

▶ **2:33 – 2:40 PM: Project Hope and Mental Health During COVID-19**

- **Rev. Karen Jackson**, Director of Community Initiatives, Project Hospitality, Administrator, SI Long Term Recovery Organization (SI LTRO)



# Agenda..cont.

- ▶ **2:40 – 2:47 PM: *SI COVID-19 Vaccine Task Force: Approaches to Vaccine Access and Education***
  - **Adrienne Abbate**, Executive Director, Staten Island Partnership for Community Wellness
- ▶ **2:47 – 2:55 PM: *Modeling Community Partnerships***
  - **Michelle Molina**, Executive Director, El Centro Del Inmigrante
- ▶ **2:55 – 3:00 PM: *Q&A***
- ▶ **3:00 – 3:15 PM: *COVID 19 Vaccine Boosters***
  - **Dr. Bindy Couch**, Director, Adult Immunization and Clinic Services, BOI Branch Director, Clinical Planning and Operations, Vaccine Section, NYC DOHMH
- ▶ **3:15 – 3:40 PM: *Mental Health Impacts of COVID-19***
  - **Dr. William Fisher**, Senior Director, Clinical Operations, Bureau of Mental Health, NYC DOHMH
- ▶ **3:40 – 3:55 PM: *Therapeutics (antivirals) and Omicron Update***
  - **Dr. Mary Foote**, Medical Director, OEPR-Bureau of Healthcare and Community Readiness, NYC DOHMH
- ▶ **3:55 – 4:00 PM: *Closing Remarks***
  - **David Miller Jr.**, Executive Director, Healthcare System Readiness, OEPR-Bureau of Healthcare and Community Readiness, NYC DOHMH
- ▶ **4:00 PM: *Adjourn***



# SI COAD Presentations

\*See separate presentation

# Updated COVID-19 Vaccine Booster Recommendations

Bindy Crouch, MD, MPH

Vaccine Section, Clinical Planning and Operations Branch  
Bureau of Immunization, Adult Immunization Unit and Clinic Services

NYC Department of Health and Mental Hygiene

# Updated Booster Recommendations

- All persons aged 18 years and older **should** receive a booster dose of COVID-19 vaccine
  - **mRNA primary series recipients:** People 18 years and older should receive a single COVID-19 booster dose at least 6 months after completion of their primary series
  - **J&J/Janssen primary series recipients:** People 18 years and older should receive a single COVID-19 booster dose at least 2 months (8 weeks) after completion of their primary series

CDC. Interim Clinical Considerations for Use of COVID-19 Vaccines Currently Approved or Authorized in the United States. Available at: <https://www.cdc.gov/vaccines/covid-19/clinical-considerations/covid-19-vaccines-us.html#booster-dose>.

# Booster Dose After an WHO-Emergency Use Listed COVID-19 Vaccine Primary Series

- People aged  $\geq 18$  years should receive a single booster dose of **Pfizer-BioNTech COVID-19 Vaccine (30  $\mu\text{g}$  formulation [purple cap])** at least 6 months after completing their primary series

CDC. Interim Clinical Considerations for Use of COVID-19 Vaccines Currently Approved or Authorized in the United States. Available at: <https://www.cdc.gov/vaccines/covid-19/clinical-considerations/covid-19-vaccines-us.html#people-vaccinated-outside-us>.



# Heterologous (“Mix-and-Match”) Doses may be Considered for Boosters but Not Additional Doses

- A dose of a different product from that used in primary series may be considered for boosters
- This does not apply to “additional doses” recommended for moderately to severely immunocompromised people who received two mRNA doses
  - Additional dose should be of the same vaccine product as the primary series (with limited exceptions)
- People who are moderately or severely immunocompromised who receive an additional mRNA dose are eligible for a single COVID-19 booster dose (Pfizer, Moderna, or Johnson & Johnson)  $\geq$  6 months after their third dose
  - Total of four COVID-19 vaccine doses

CDC. Interim Clinical Considerations for Use of COVID-19 Vaccines Currently Approved or Authorized in the United States. Available at: <https://www.cdc.gov/vaccines/covid-19/clinical-considerations/covid-19-vaccines-us.html#booster-dose>.

# FDA-Authorized or Approved COVID-19 Vaccines for Primary or Booster Vaccination

Vaccine	Primary series/dose				Booster dose	
	Dose (volume)	No. doses (interval)	Age (yrs)	Interval from primary to booster dose	Dose (volume)	Age (yrs)
<b>Pfizer-BioNTech</b>	30 µg (0.3 ml)	2 (21 days)	≥12	≥6 months	30 µg (0.3 ml)	≥18
<b>Moderna</b>	100 µg (0.5 ml)	2 (28 days)	≥18	≥6 months	<b>50 µg (0.25 ml)</b>	≥18
<b>Janssen</b>	5 × 10 <sup>10</sup> VP (0.5 ml)	1 (N/A)	≥18	≥2 months	5 × 10 <sup>10</sup> VP (0.5 ml)	≥18

- Note: booster dose of Moderna vaccine is half the amount used for the primary **Moderna** series; **half dose given regardless of what vaccine product used for the primary series**

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# Individual Risk-Benefit Assessment for Choice of Booster Product

- May take risk of rare adverse events associated with specific vaccine products into account
- Johnson & Johnson
  - Thrombosis with thrombocytopenia, highest risk for women aged 18-49 years
  - Guillain-Barre Syndrome, highest risk for men aged 50-64 years
- mRNA vaccines
  - Myocarditis and pericarditis, highest risk for males aged 12-30 years

CDC. Interim Clinical Considerations for Use of COVID-19 Vaccines Currently Approved or Authorized in the United States. Available at: <https://www.cdc.gov/vaccines/covid-19/clinical-considerations/covid-19-vaccines-us.html#booster-dose>.

# Pediatric and Adult Flu Vaccination Update

# Co-administer Flu Vaccine with COVID-19 Vaccine

- COVID-19 vaccines may be administered without regard to timing of other vaccines, including on the same day as other vaccines.
- If multiple vaccines are administered during a single visit
  - Administer each in a different injection site
  - Separate injection by  $\geq 1$  inch
  - For people  $\geq 11$  years, deltoid muscle can be used
  - For children 5-10 years, if  $\geq 2$  vaccines are injected in a single limb, vastus lateralis muscle of anterior thigh is the preferred site due to greater muscle mass

CDC. Interim Clinical Considerations for Use of COVID-19 Vaccines Currently Approved or Authorized in the United States. Available at: <https://www.cdc.gov/vaccines/covid-19/clinical-considerations/covid-19-vaccines-us.html#Coadministration>.

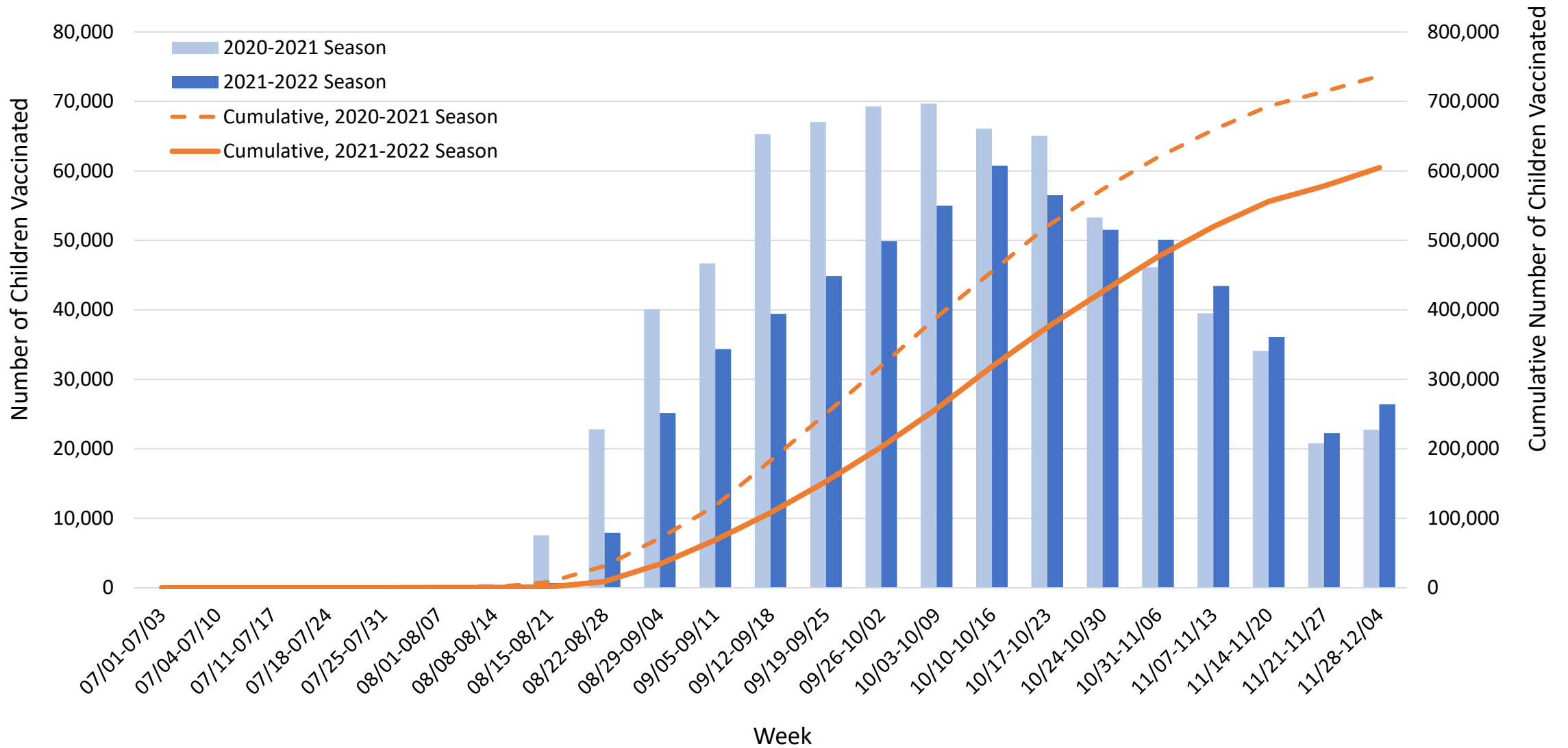
## Number of Children Aged 6 Months to 18 Years Vaccinated With $\geq 1$ Flu Vaccine Dose, NYC (July 1 – Dec 4)

Age Group	2021-22 Influenza Season (YTD*)	2020-21 Influenza Season (YTD*)	Percent Change
6-59 Months	184,935	223,340	-17.2
5-8 Years	138,665	164,839	-15.9
9-18 Years	280,954	347,072	-19.1
<b>All Children Aged 6 Months to 18 Years</b>	<b>604,554</b>	<b>735,251</b>	<b>-17.8</b>

Source: NYC DOHMH Citywide Immunization Registry; data run on 12/7/2021

\*Year-to-Date (YTD): Flu doses administered between 7/1 and 12/4 and reported to the CIR by 12/5

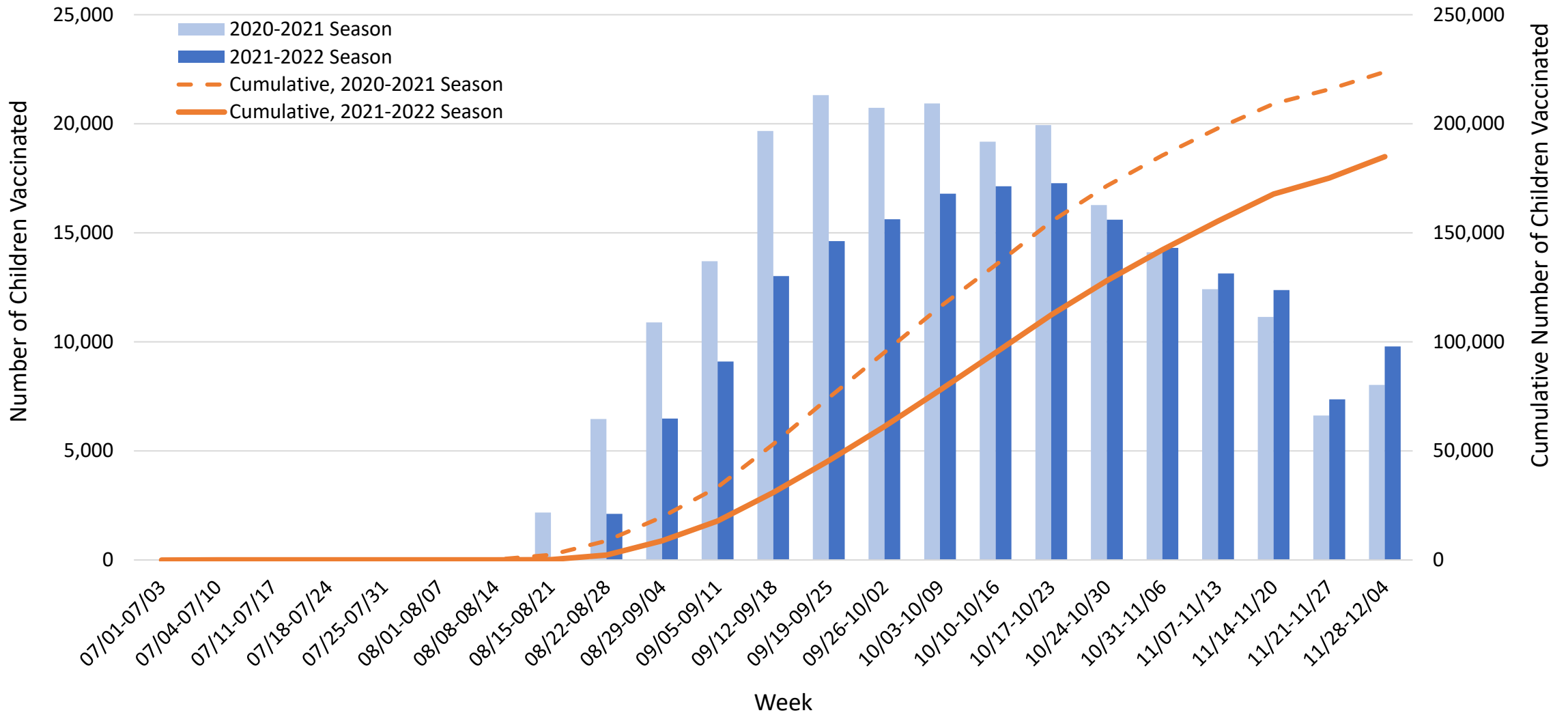
## Number of Children Aged 6 Months to 18 Years Who Received $\geq 1$ Flu Vaccine during the 2020-2021 and 2021-2022 Influenza Seasons, by Week



Source: NYC DOHMH Citywide Immunization Registry; data run on 12/7/2021  
 \*Flu data entered into the CIR by 12/6/2020 for the 2020-2021 influenza season  
 \*\*Flu data entered into the CIR by 12/5/2021 for the 2021-2022 influenza season

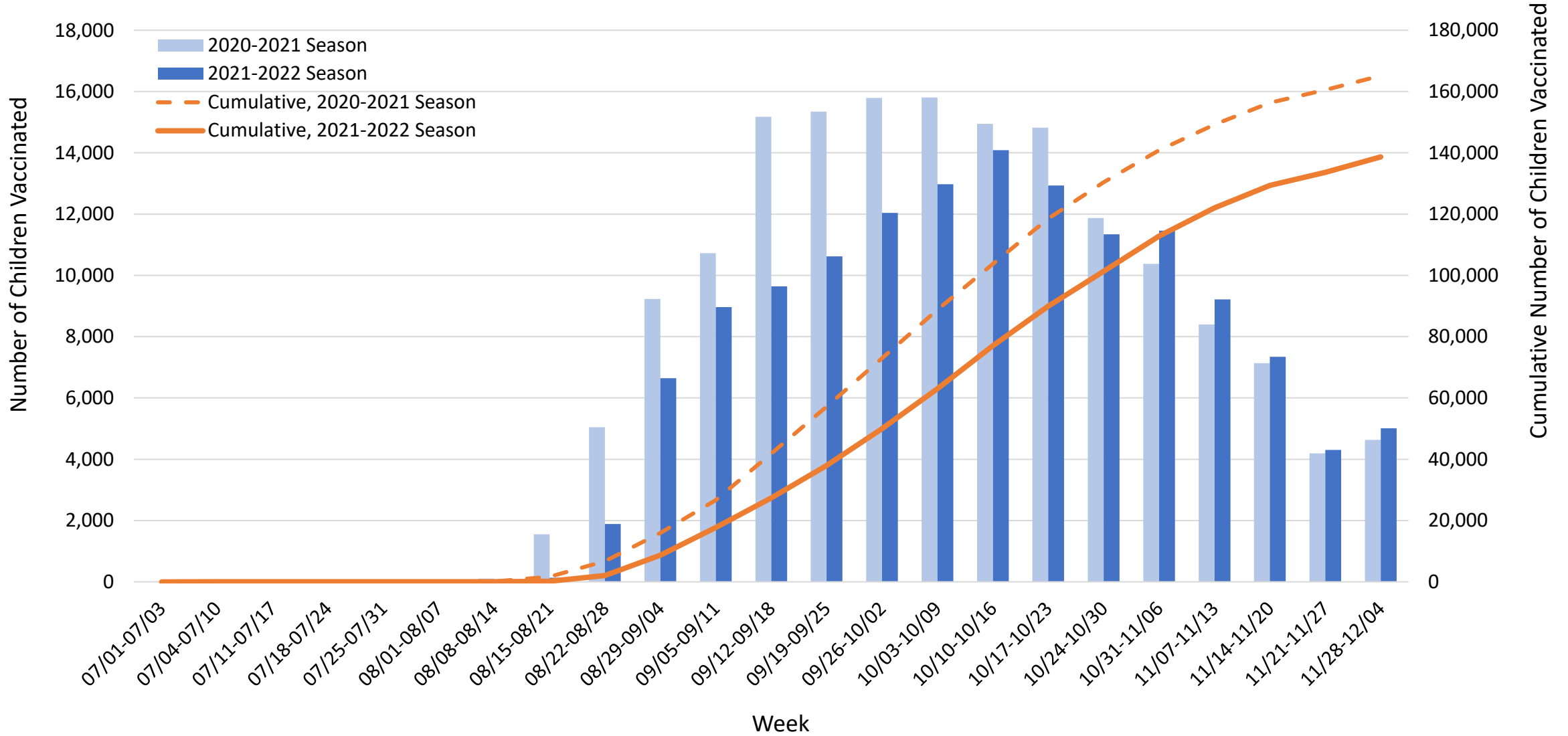


## Number of Children Aged 6 to 59 Months Who Received $\geq 1$ Flu Vaccine during the 2020-2021 and 2021-2022 Influenza Seasons, by Week



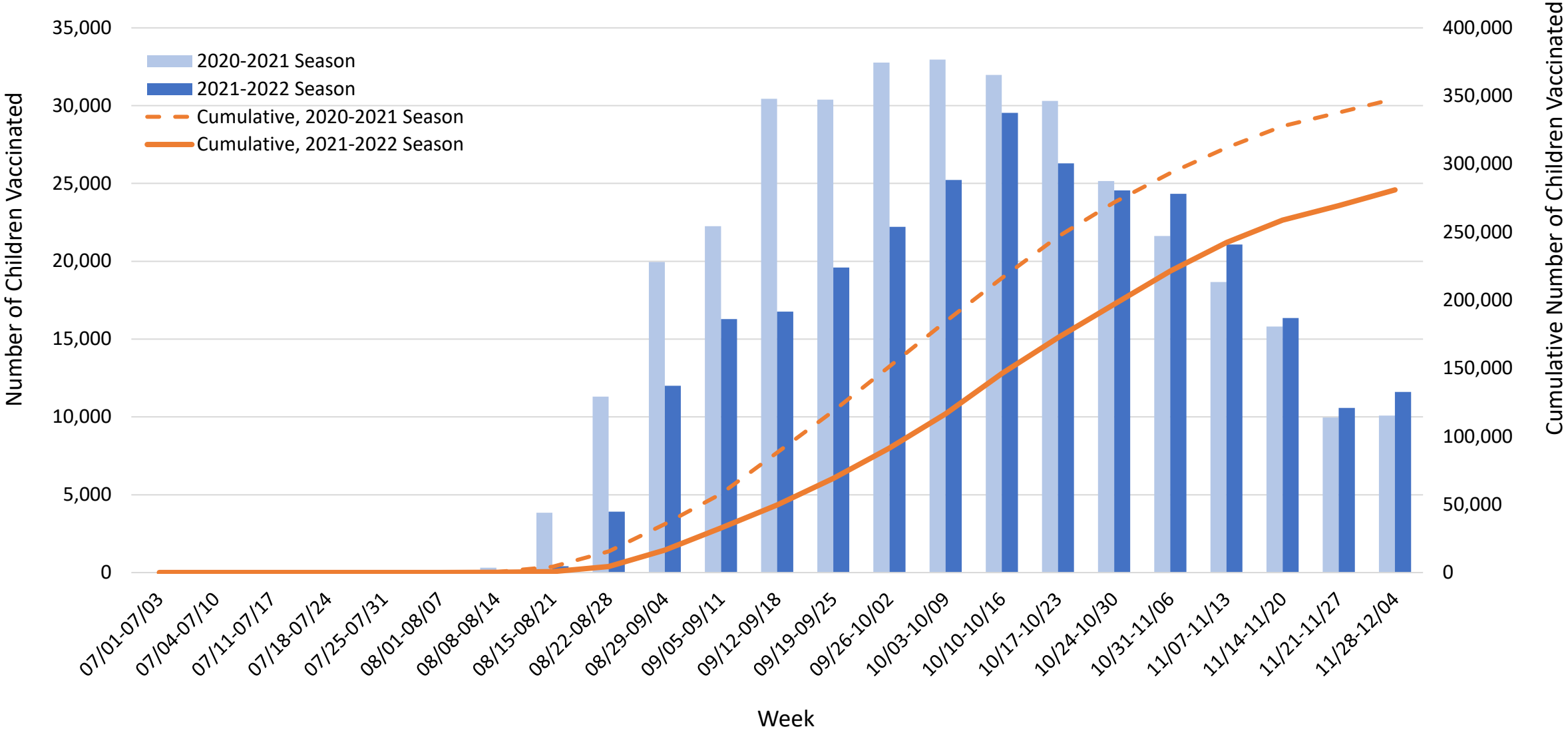
Source: NYC DOHMH Citywide Immunization Registry; data run on 12/7/2021  
 \*Flu data entered into the CIR by 12/6/2020 for the 2020-2021 influenza season  
 \*\*Flu data entered into the CIR by 12/5/2021 for the 2021-2022 influenza season

## Number of Children Aged 5 to 8 Years Who Received $\geq 1$ Flu Vaccine during the 2020-2021 and 2021-2022 Influenza Seasons, by Week



Source: NYC DOHMH Citywide Immunization Registry; data run on 12/7/2021  
 \*Flu data entered into the CIR by 12/6/2020 for the 2020-2021 influenza season  
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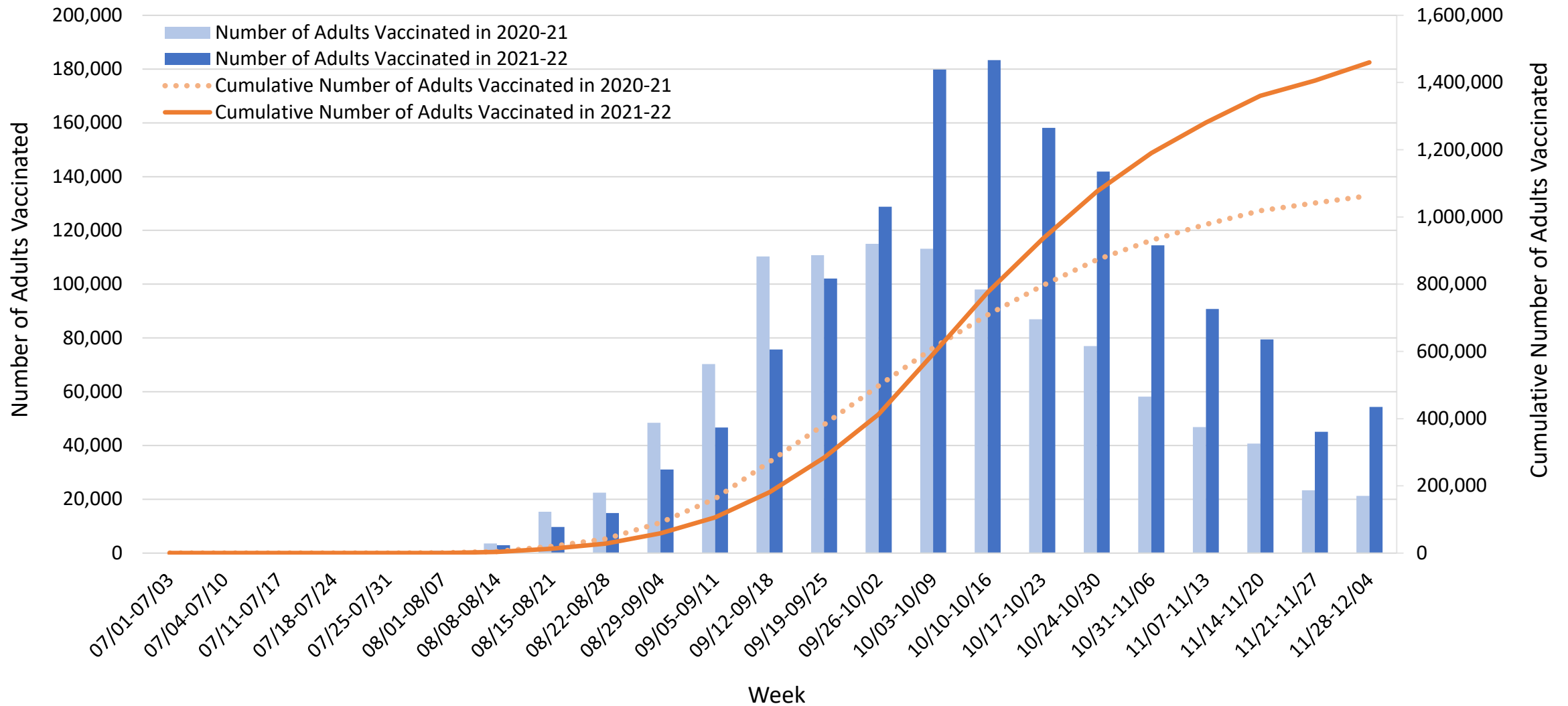
# Number of Children Aged 9 to 18 Years Who Received $\geq 1$ Flu Vaccine during the 2020-2021 and 2021-2022 Influenza Seasons, by Week



Source: NYC DOHMH Citywide Immunization Registry; data run on 12/7/2021  
 \*Flu data entered into the CIR by 12/6/2020 for the 2020-2021 influenza season  
 \*\*Flu data entered into the CIR by 12/5/2021 for the 2021-2022 influenza season



## Number of Adults Aged 19 Years and Older Who Received $\geq 1$ Flu Vaccine during the 2020-2021 and 2021-2022 Influenza Seasons, by Week



Source: NYC DOHMH Citywide Immunization Registry; data run on 12/7/2021  
 \*Flu data entered into the CIR by 12/6/2020 for the 2020-2021 influenza season  
 \*\*Flu data entered into the CIR by 12/5/2021 for the 2021-2022 influenza season

# Questions/Comments

Bindy Crouch  
[bcrouch1@health.nyc.gov](mailto:bcrouch1@health.nyc.gov)

# Mental Health Impacts of the COVID-19 Pandemic

Results of the Emotional Wellness Survey, Health Opinion Polls and New York City  
Department of Health and Mental Hygiene Surveillance Activities

William A. Fisher, M.D.

Senior Director of Clinical Services, Bureau of Mental Health  
Division of Mental Hygiene, NYC Department of Health and Mental Hygiene

# Emotional Wellness Survey Sampling Methodology

- Fielded primarily in January
- Participants sampled from Division of Epidemiology's Healthy NYC panel: Around 10,000 probability-based panel designed to be representative of non-institutionalized adults living in New York City (NYC)
- Selected using stratified random sampling
- Self-administered online and mailed in English, Spanish, Chinese and Russian, with a post-completion incentive
- Data weighted to represent NYC per 2019 American Community Survey
- Of the **2,410** invited to participate, **1,048** completed the survey. The participation rate was **43.5%**.

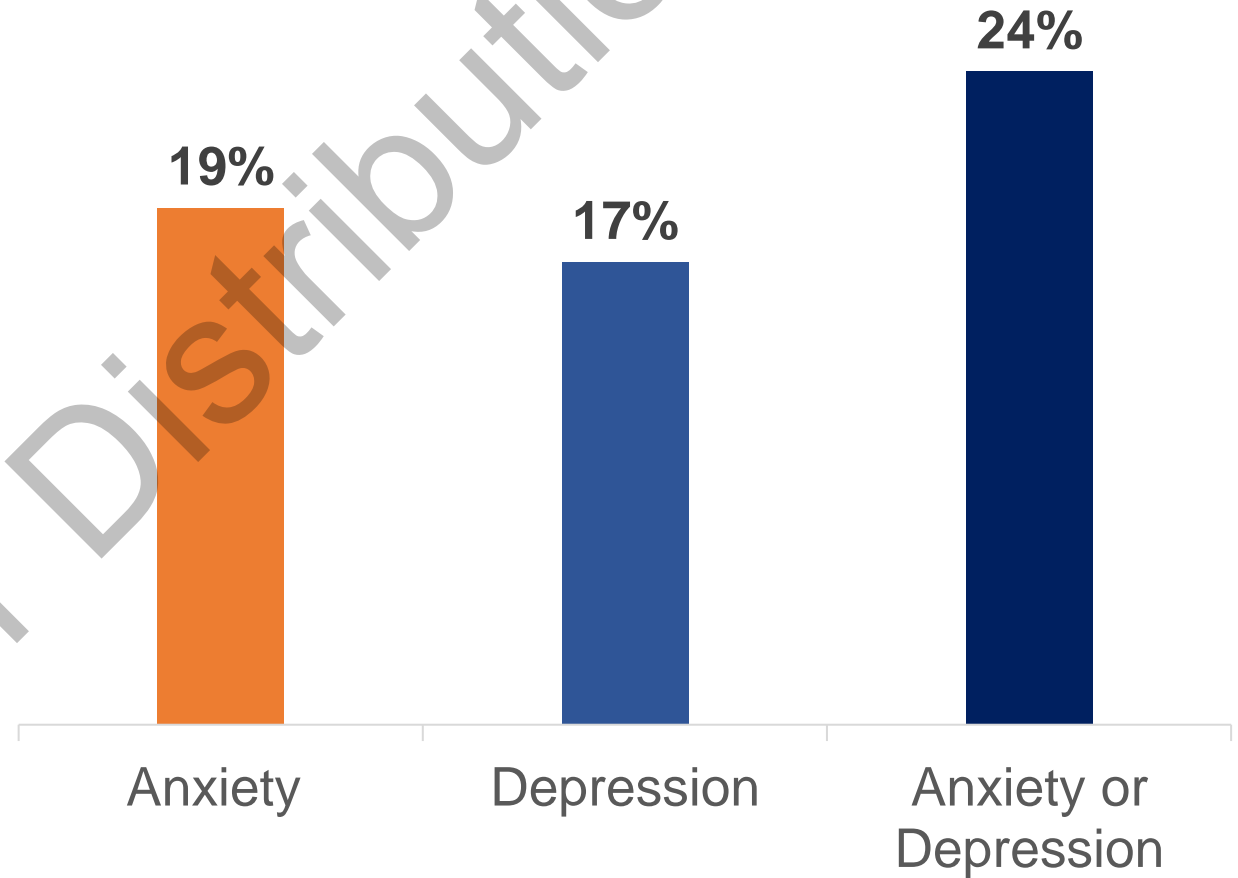
# Depression in NYC

- Question: “Over the last 2 weeks, how often have you been bothered by the following problems?”
  - Feeling nervous, anxious or on edge (GAD-2)
  - Not being able to stop or control worrying (GAD-2)
  - Feeling down, depressed or hopeless (PHQ-2)
  - Little interest or pleasure in doing things (PHQ-2)
- Percent of respondents who scored  $\geq 3$  out of 6 on the Generalized Anxiety Disorder (GAD-2) and Patient Health Questionnaire (PHQ-2) indicating probable anxiety or depression warranting further evaluation.
- Depression remains above pre-pandemic levels, but has stabilized since March 2021.

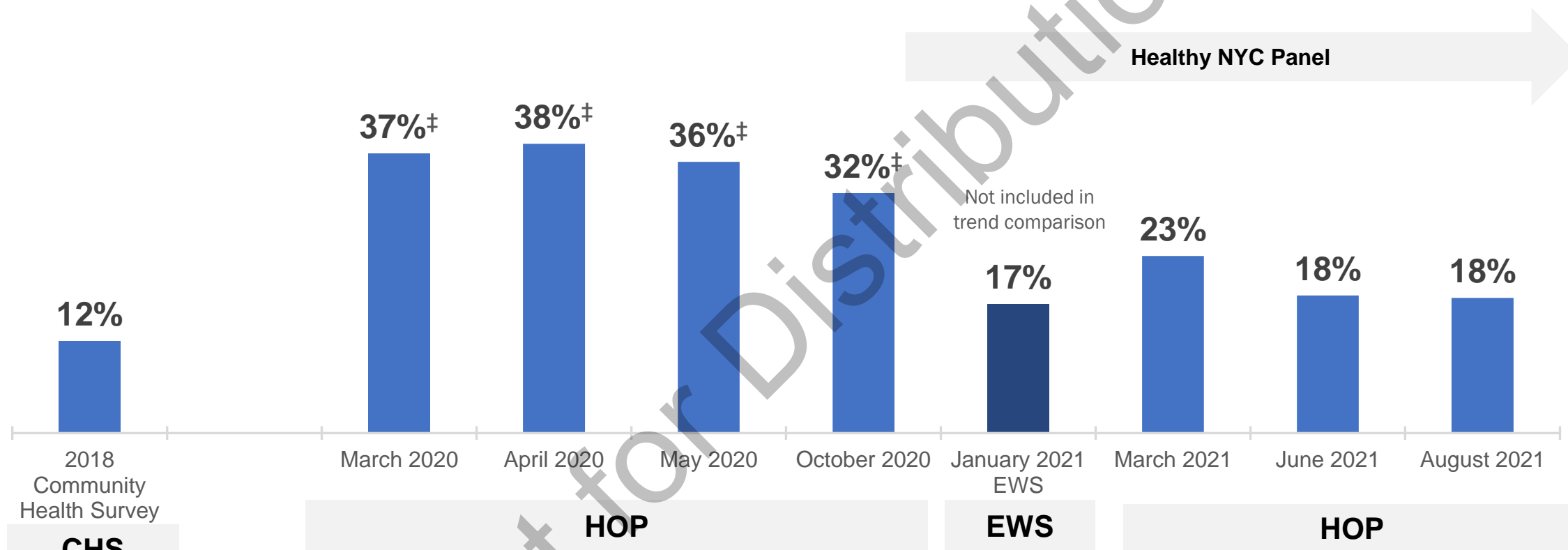


# Depression in NYC

About one in four adults reported symptoms of anxiety or depression



# Depression Trends in NYC

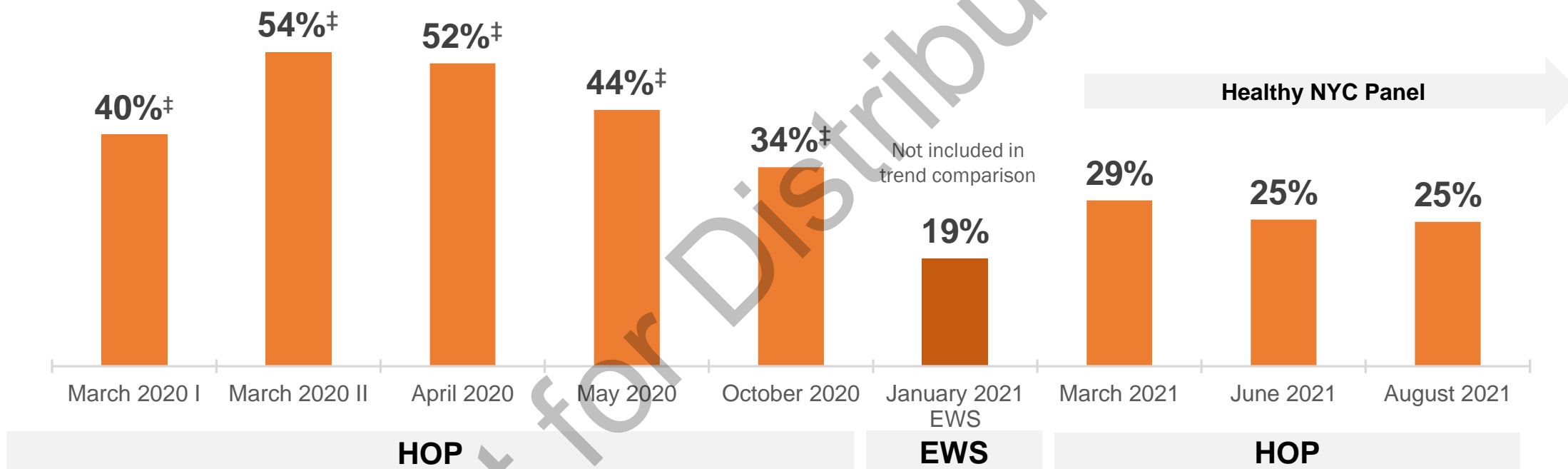


‡ Significantly different from reference group

Evaluation of change over time should be interpreted with caution. Prior to HOP-12 (March 2021), HOP surveys were implemented using non-probability online panels, while surveys from March 2021 onward were completed by members of a probability-based panel.

# Anxiety Trends in NYC

- Prevalence of anxiety is high, but has stabilized since March 2021



‡ Significantly different from reference group

Evaluation of change over time should be interpreted with caution. Prior to HOP-12 (March 2021), HOP surveys were implemented using non-probability online panels, while surveys from March 2021 onward were completed by members of a probability-based panel.

# Prevalence of Anxiety or Depression

‡ Significantly different from reference group

\* Estimate potentially unreliable and should be interpreted with caution

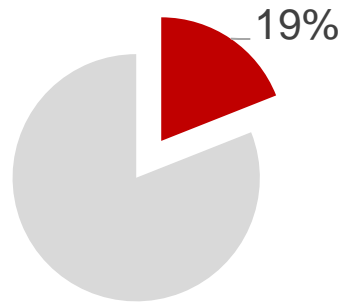


# Financial Challenges During COVID

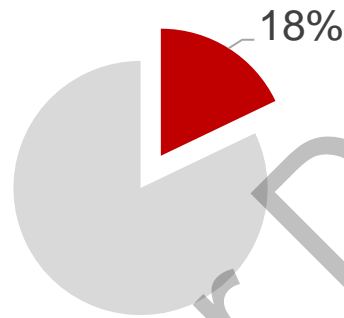
- 31% of individuals had overwhelming or above average financial stress.
- Question: “What do you feel is the level of your financial stress today?”
  - Overwhelming or above average// Some or average//No stress
- 45% of individuals experienced unemployment or reduced pay.
- Question: “Are you or someone in your household currently unemployed or experiencing reduced pay or income because of COVID-19?”
  - Yes (myself or household) // No”

# Financial Challenges During COVID (continued)

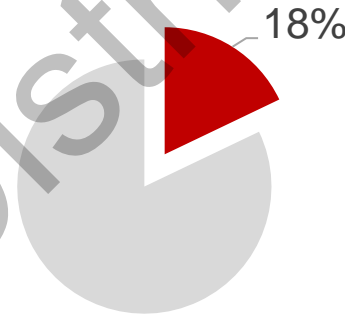
- 33% of respondents experienced one or more of these stressors in the past four weeks:



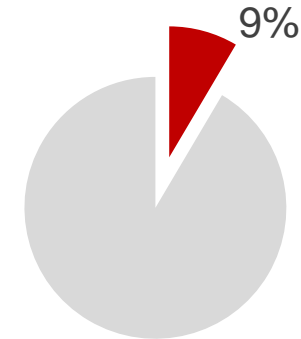
19% were unable to pay rent or mortgage



18% were unable to pay their utility bill



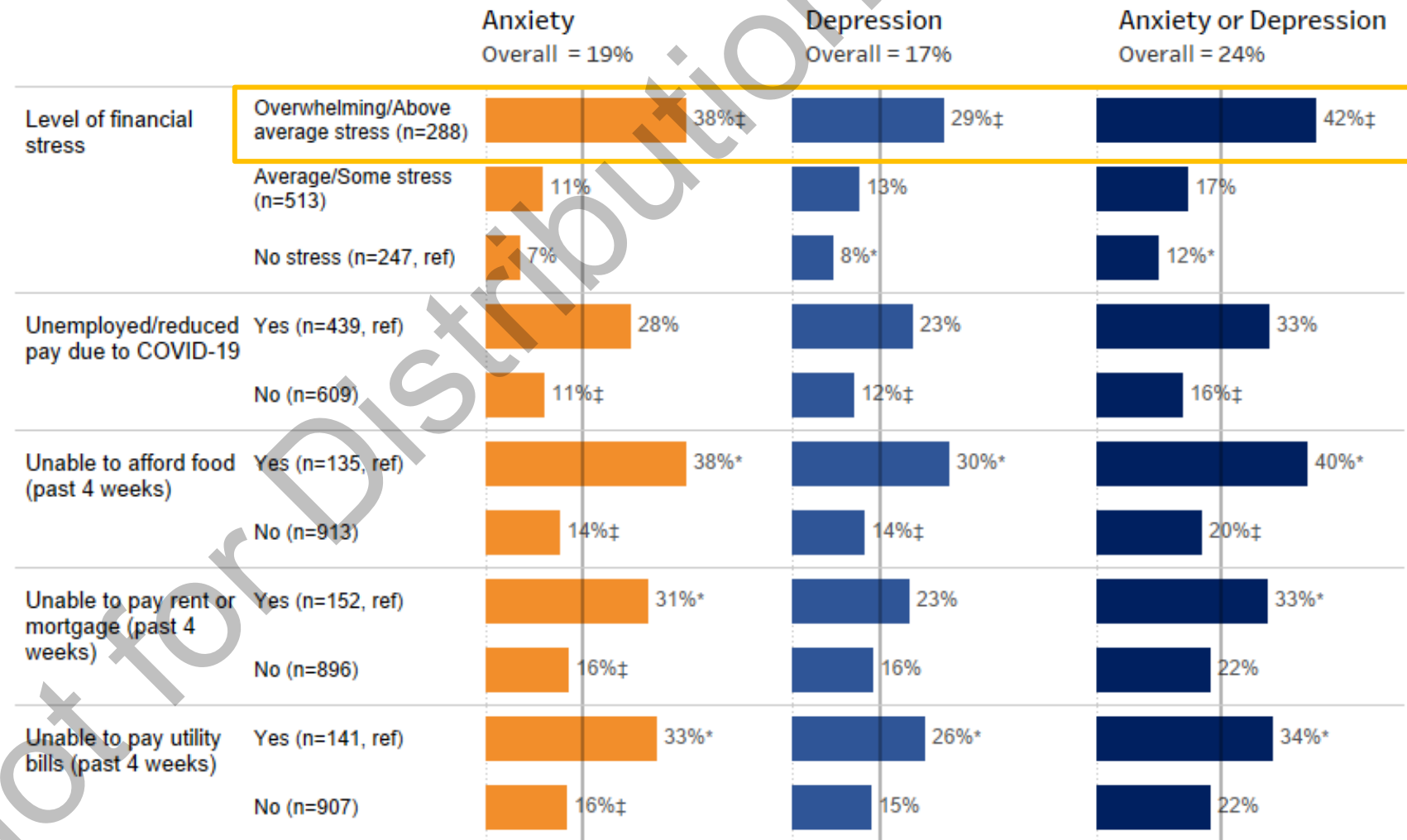
18% did not have enough money for food



9% did not have enough money to see a doctor

“In the past 4 weeks did you experience the following:”

# Anxiety, Depression and Financial Stress (continued)



# Anxiety, Depression and Financial Stress

- Anxiety or depression was three times more likely among adults with overwhelming/above average financial stress compared to those without.
- Questions:
  - “What do you feel is the level of your financial stress today?”
  - “Are you or someone in your household currently unemployed or experiencing reduced pay because of COVID-19?”

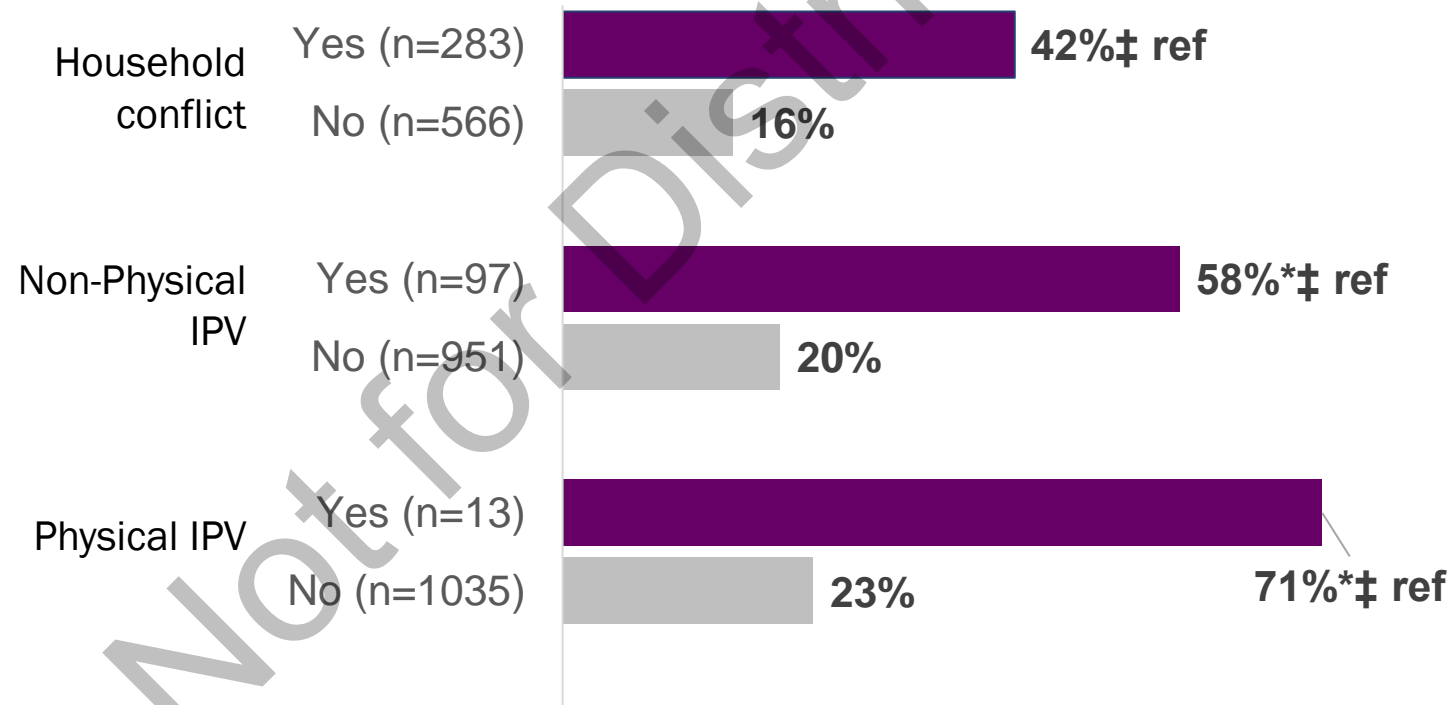


# Anxiety, Depression and Domestic Violence

- Since March 2020:
  - New Yorkers experienced a 30% increase in verbal arguments or conflicts in the household.
  - 10% of individuals experienced non-physical forms of intimate partner violence (IPV), such as harassment and verbal abuse.
  - 1% of individuals experienced physical forms of IPV.

# Anxiety, Depression and Domestic Violence

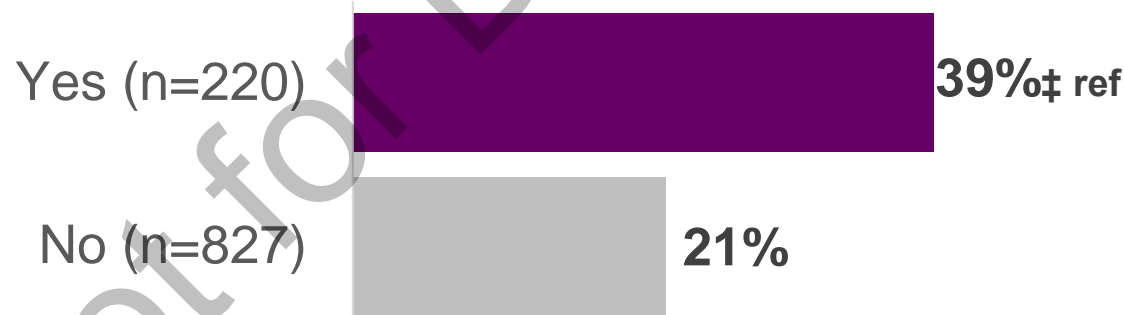
Percentage of people reporting symptoms of anxiety or depression



# Anxiety, Depression and Caregivers

- 18% of respondents reported being an unpaid caregiver for an adult.
- 39% of unpaid caregivers reported symptoms of anxiety or depression.

Are you experiencing symptoms of anxiety or depression?



# Anxiety, Depression and Loneliness

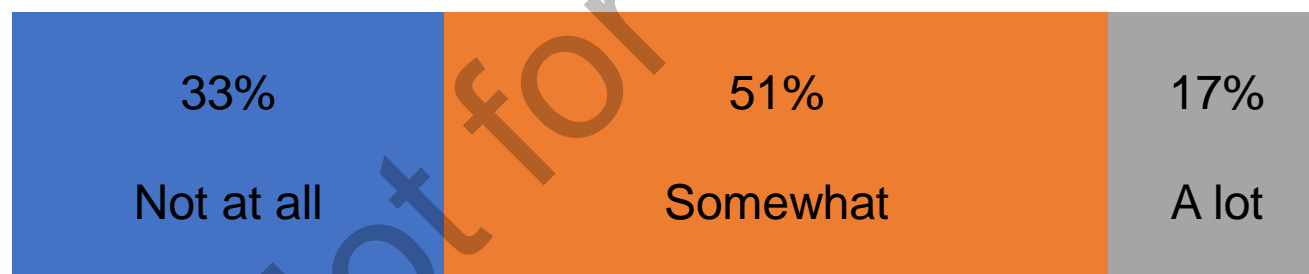
- 12% of adults report feeling lonely “often.”
- Question: “How often do you feel lonely?”
  - Hardly ever or never // Some of the time // Often



August 2021 HOP found 10% “often” lonely

# Anxiety, Depression and Loneliness (continued)

- 17% of adults report feeling socially isolated “a lot.”
- Question: “How much have you been feeling cut off or distant from other people, even people you used to be close to like family or friends?”
  - Not at all // Somewhat // A lot



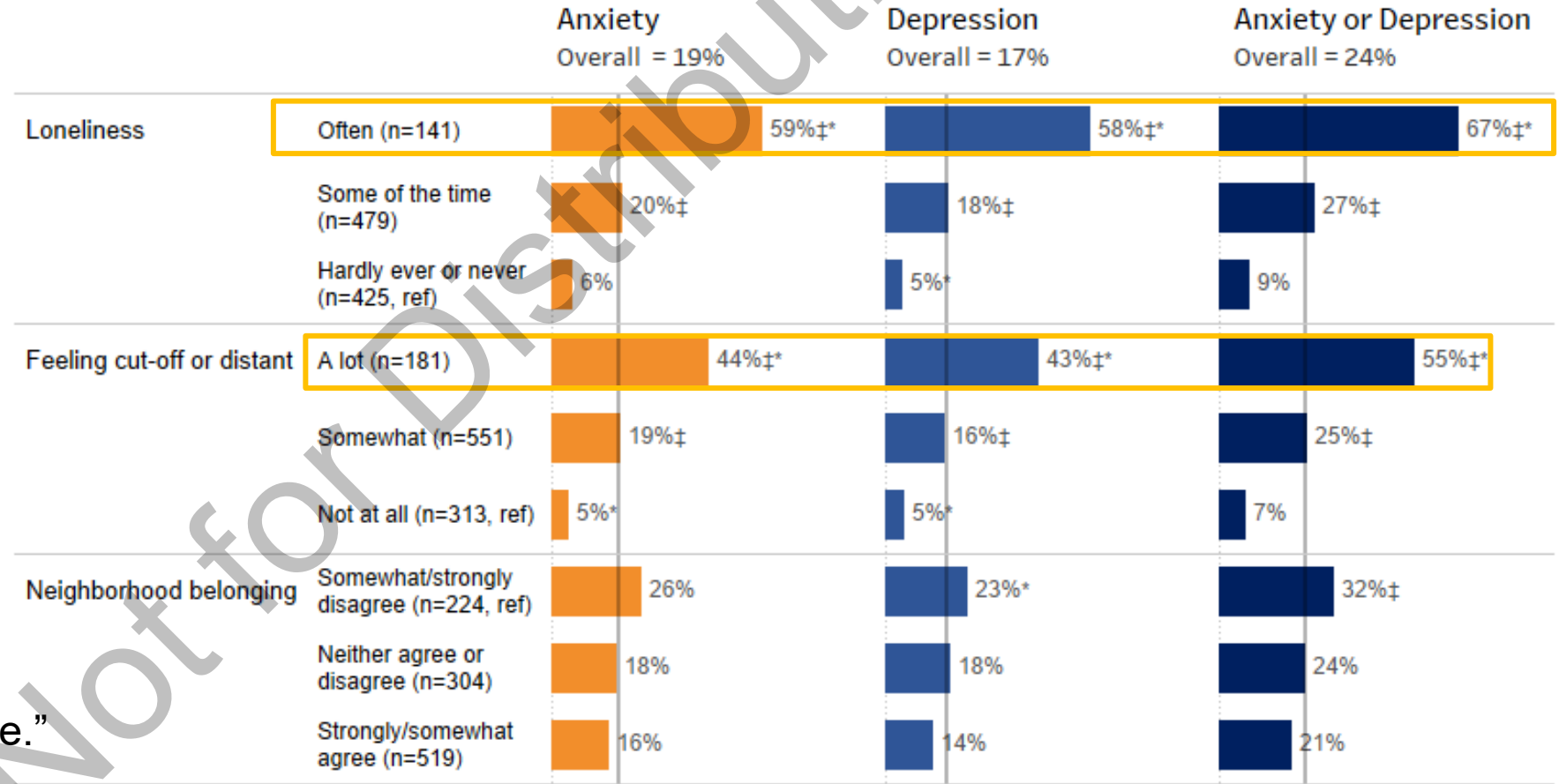
# Anxiety, Depression and Loneliness (continued)

Questions:

“How often do you feel lonely?”

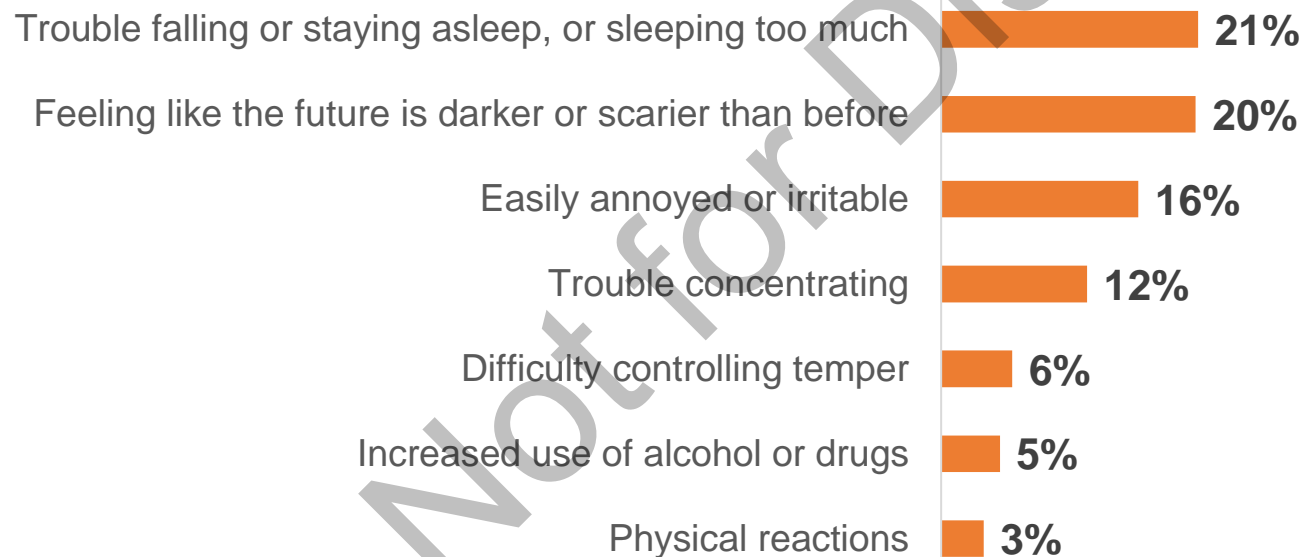
“How much have you been feeling cut off or distant from other people like family or friends?”

“I feel like a part of my neighborhood, like I belong there.”



# Mental and Physical Stress

- Question: “In the past four weeks, how often has worry or stress related to the COVID-19 public health emergency caused you to experience...”
  - Never // Some days // Most days // Every day



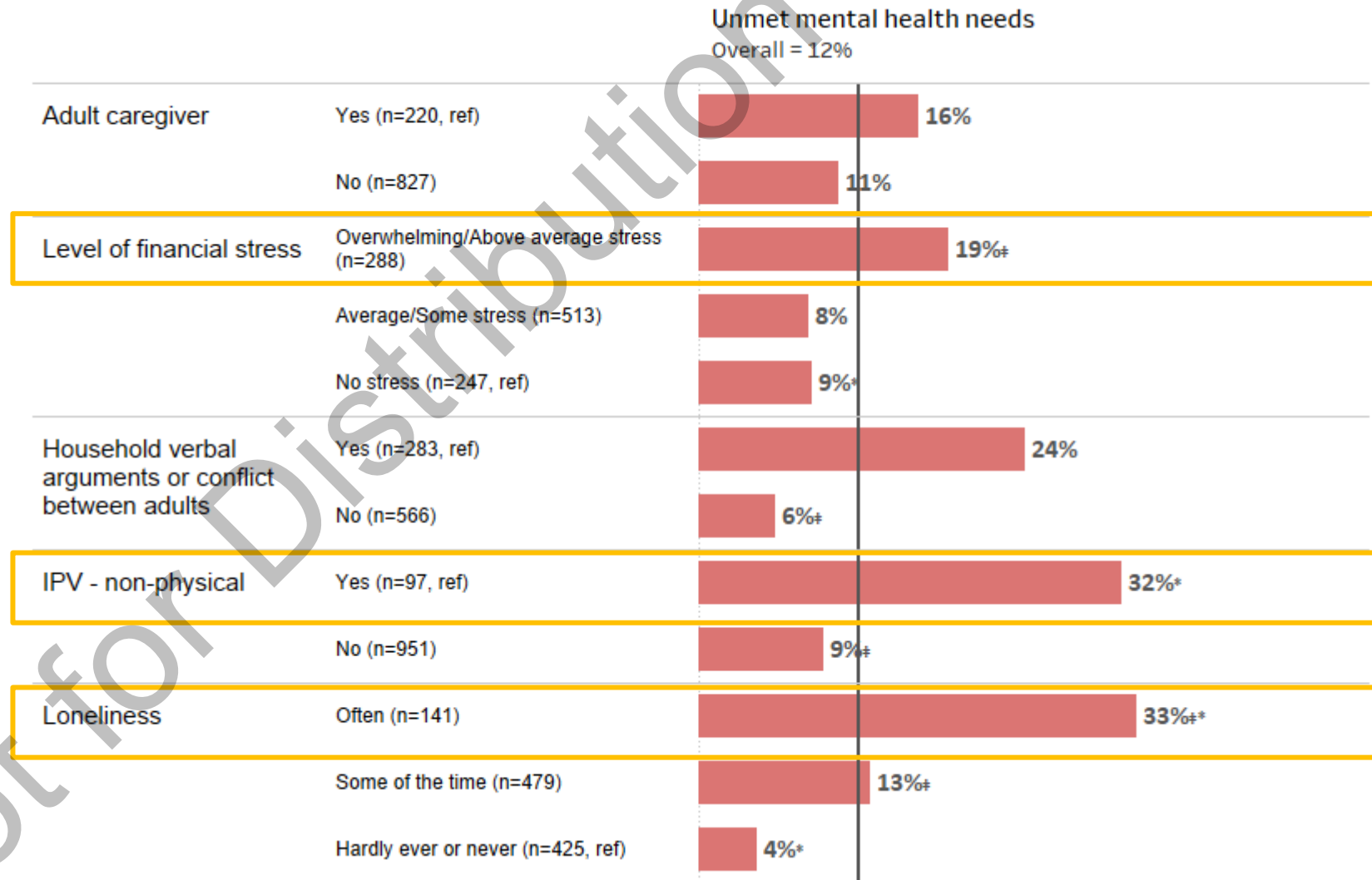
# Mental Health Needs

- 23% of respondents needed more emotional support.
- Question: “In the past four weeks, did you need more emotional support than you were getting?”
  - Yes // No
- 32% of adults with anxiety or depression had unmet mental health treatment needs.
- Question: “In the past 12 months, was there a time when you needed treatment for a mental health problem, but did not get it?”
  - Yes // No



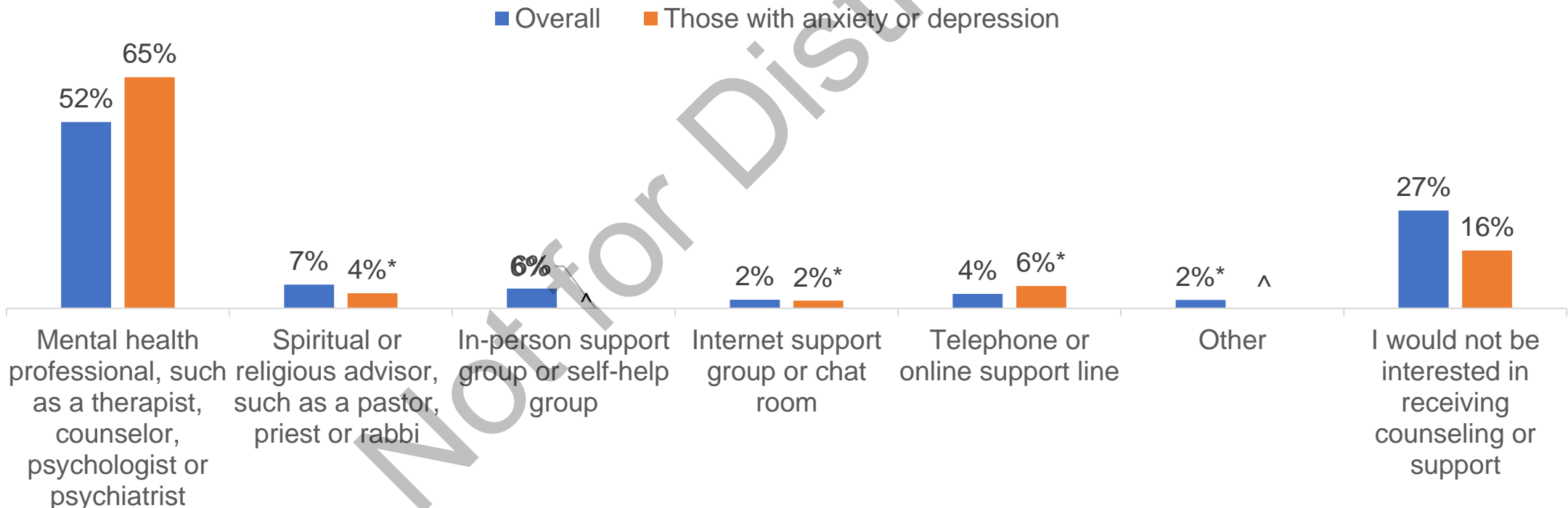
# Mental Health Needs (continued)

- Unmet mental health needs were higher among those experiencing financial stress, loneliness and IPV.



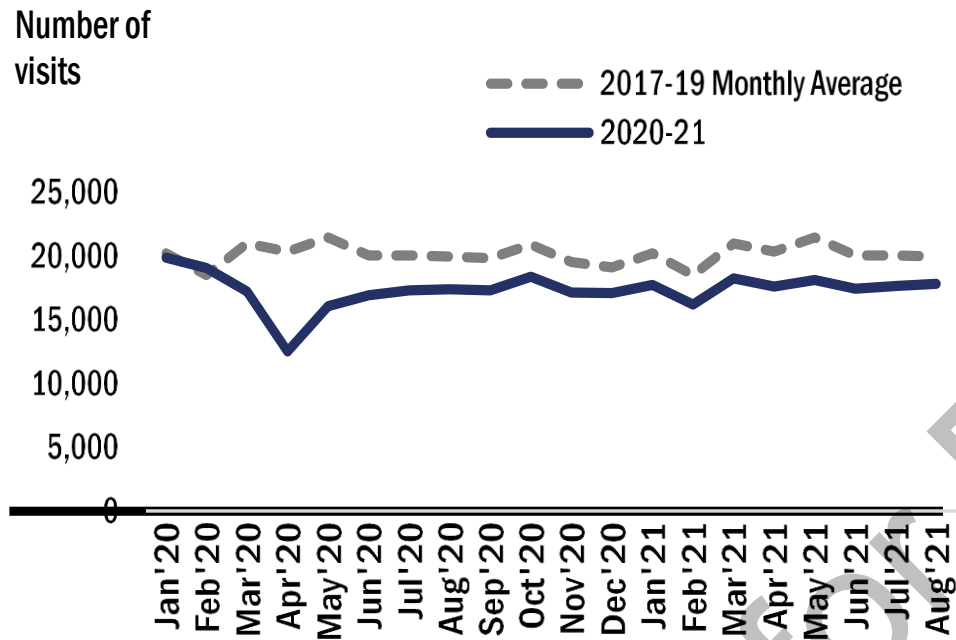
# Mental Health Needs (continued)

“If you need counseling or support for your emotions, nerves or mental health, how would you be most interested in getting it?”



### Mental health emergency department visits before and during the COVID-19 pandemic, by month, New York City

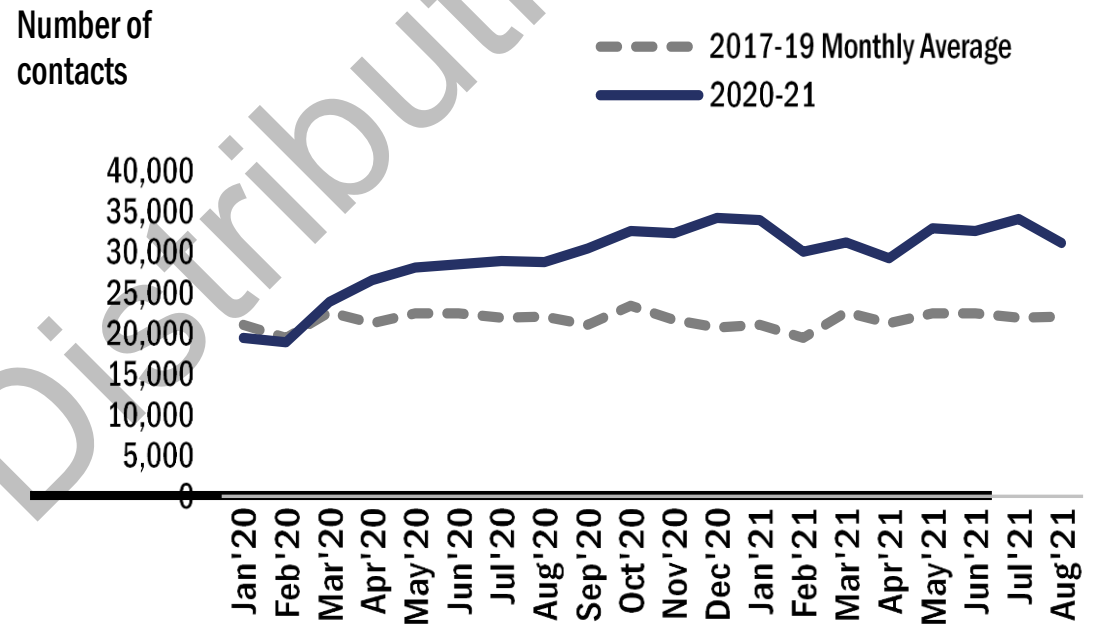
Average number of visits January 2020-August 2021 versus 2017-2019



Source: NYC DOHMH Syndromic Surveillance data, Bureau of Communicable Diseases. Extracted September 2021

### NYC Well contacts before and during the COVID-19 pandemic, by month, New York City

Average number of contacts January 2020-August 2021 versus 2017-2019



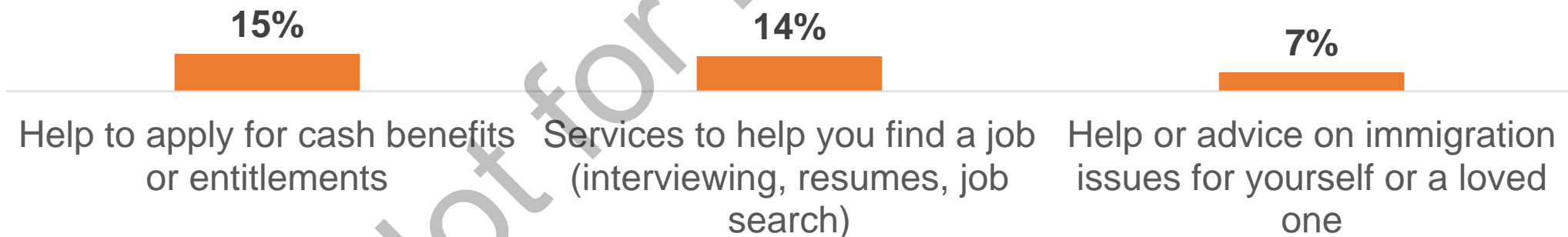
NYC Well support service contacts include answered calls, texts, and chats  
 Source: NYC Well Administrative data. Extracted September 2021

\*Estimate should be interpreted with caution. Estimate's Relative Standard Error (a measure of estimate precision) is greater than 30%, or the 95% Confidence Interval half-width is greater than 10 or the sample size is too small, making the estimate potentially unreliable.

# Accessing or Applying for Services

- Adults in NYC needed assistance with applying for cash benefits, job searching and immigration issues.

“In the past four weeks, did you need the following...”



# COVID-19 and People Who Use Drugs

- People who use drugs (PWUD) in the U.S. are at increased risk for severe illness and death due to COVID-19 infection.
- Stigma and discrimination against PWUD within the health care system create and promote distrust, resulting in:
  - Worse health outcomes due to PWUD avoiding treatment or being undertreated when they do access services
  - PWUD turning to information sources that are less reliable and embracing misinformation and disinformation
- PWUD can face structural barriers to vaccination and receipt of health care, such as:
  - Cost of transportation or co-pays for medical appointments
  - Ability to take time off work for appointments

# Survey Overview

- Our survey was conducted approximately one year into the COVID-19 public health emergency, after the Food and Drug Administration (FDA) authorized vaccines for emergency use.
- The survey sought to assess the following:
  - Perceptions of COVID-19 vaccine safety and attitudes regarding vaccination in general
  - Use of and confidence in various information sources
  - Understanding, experience, and beliefs of COVID-19 and the COVID-19 vaccines
- **Survey demographics:**
  - 80% male
  - Most participants were ages 30 to 60 years
  - 22% non-Hispanic Black, 44% Hispanic and 30% non-Hispanic White
    - 68% Hispanic interviewees were Puerto Rican
  - One-third of participants reported receiving services from syringe services programs
  - Over half of the interviews were conducted in the Bronx, followed by Manhattan and Queens

# Results

- 62% of those not yet vaccinated against COVID-19 said they would not accept a COVID-19 vaccine if offered.
- 40% of those reporting being unwilling to receive a COVID-19 vaccine were not very confident in that decision.
- Older adults were more willing to be vaccinated against COVID-19.
- Those having an associate's degree or at least some college education were more willing to be vaccinated against COVID-19 .
- Non-Hispanic White participants were significantly less likely to be willing to receive a COVID-19 vaccine than those of other race and ethnicities.

# Feelings About COVID-19 Vaccination

- Participants reported thinking that vaccination is important to the health of the community.
- Participants also thought that their personal decision to be vaccinated was important to the health of others.
- However, two-thirds of participants reported being unwilling to get vaccinated against COVID-19.
  - Among those who reported being unwilling to be vaccinated, 40% were not confident in this decision.
- Survey results suggest that PWUD had mixed feelings regarding COVID-19 vaccination.



# Behavioral Health Resources

Not for Distribution

# COVID-19 Community Conversations (3C)

- There are two types of trainings:
- The **one-hour virtual conversation** talks about:
  - The impact of COVID-19 on mental health
  - Disparities in communities of color
  - Grief and trauma
  - Tips for self-care
  - Mental health and local resources

# COVID-19 Community Conversations (continued)

- **The Three Hour Virtual Training:**
  - Builds on Phase I
  - Is interactive, expansive and skills-based
  - Is four modules:
    - Impact of COVID-19
    - Stress, Trauma and Mental Health
    - COVID-19, Equity, and Social Justice
    - Self and Community Care

# COVID-19 Community Conversations (continued)

- For individuals who would like to register, we offer borough-specific public trainings.
  - Queens: [queens\\_covidconvo.timetap.com](https://queens_covidconvo.timetap.com)
  - Brooklyn: [brooklyn\\_covidconvo.timetap.com](https://brooklyn_covidconvo.timetap.com)
  - Bronx: [bronx\\_covidconvo.timetap.com](https://bronx_covidconvo.timetap.com)
  - Staten Island: [statenisland\\_covidconvo.timetap.com](https://statenisland_covidconvo.timetap.com)
  - Manhattan: [manhattan\\_covidconvo.timetap.com](https://manhattan_covidconvo.timetap.com)
- For organizations that would like to have their own training, please email [covidconvo@health.nyc.gov](mailto:covidconvo@health.nyc.gov).

# Emotional Support

- **NYC Well:** For brief, confidential counseling and connection to support services, call 888-NYC-WELL (888-692-9355), text “WELL” to 65173, or chat online at [nyc.gov/nycwell](https://nyc.gov/nycwell). Support is available 24/7, in over 200 languages.
- **NY Project Hope, New York’s COVID-19 Emotional Support Helpline:** Call 844-863-9314, 8 a.m. to 10 p.m., seven days a week. Local crisis counselors are also available in all five boroughs of NYC. You can be connected with a crisis counselor by visiting [nyprojecthope.org/providers](https://nyprojecthope.org/providers).
- **NYC Frontline Essential Workers (FEW) Hotline:** The NYC FEW Hotline is free, confidential, and available to all NYC community-based providers and essential workers in emotional distress. Call 866-565-7715, 10 a.m. to 10 p.m., Monday through Friday.

**Thank you!**

Not for Distribution

# Updates on Variants and therapeutics

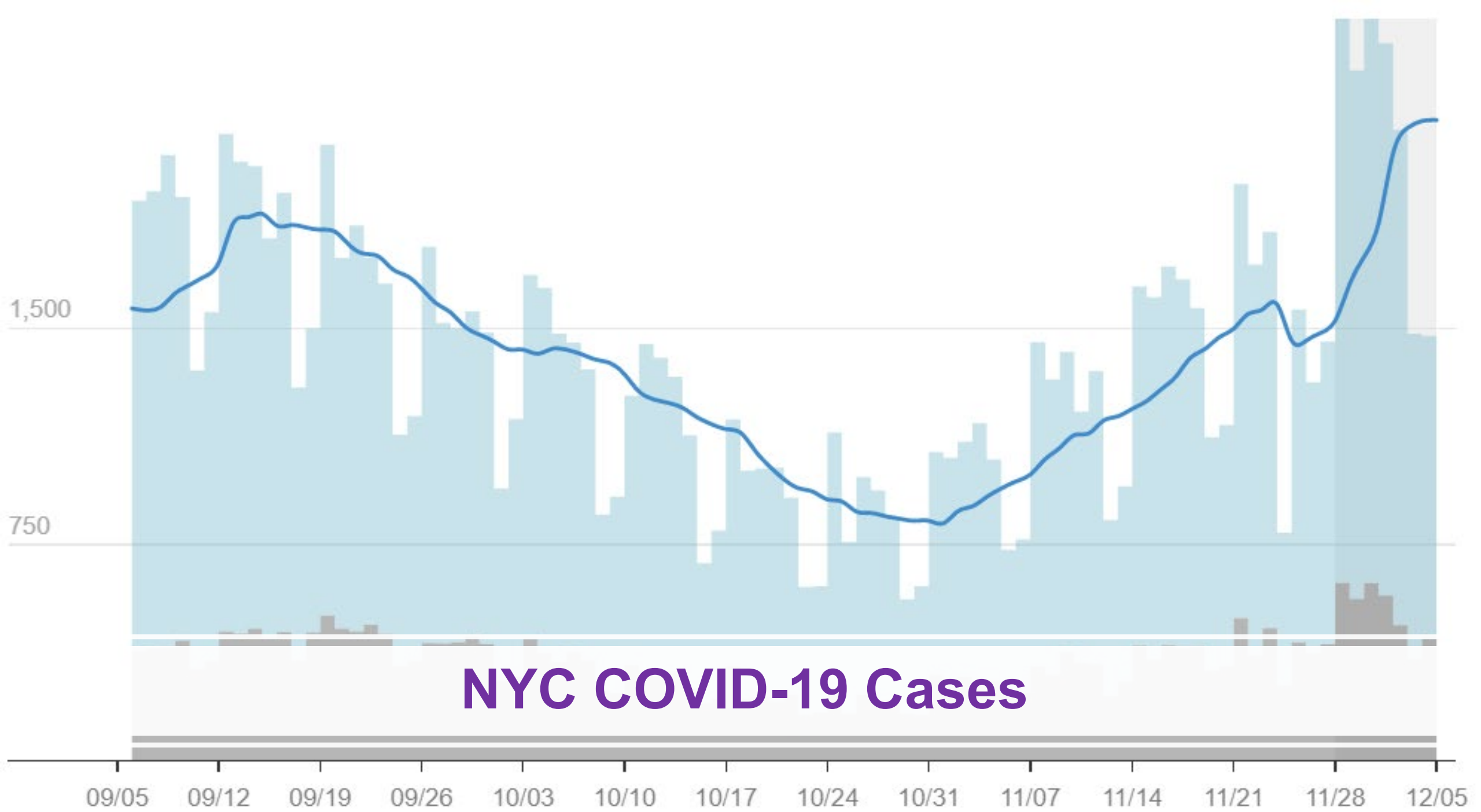
Mary Foote, MD, MPH

Medical Director/Healthcare Systems Support Branch Director (COVID-19  
Response)

New York City Department of Health and Mental Hygiene

# Epi Updates and Variant Surveillance





# NYC COVID-19 Cases

# Confirmed positive COVID-19 patients currently hospitalized, by borough, from 07.01.21

NYS Health Emergency Response Data System (HERDS)  
DOHMH//2020 Novel Coronavirus Response (COVID-19)//Integrated Data Team

December 7, 2021

Health

Data provided here are raw data pulled directly from HERDS and have not been validated in any way by the NYC or NYS Health Departments. These data should NOT be reported publicly and should NOT be assumed to be correct.

Data as of:

December 6, 2021

Note that these data are not restricted to patients admitted through the Emergency Department.

## Latest Numbers

Citywide: 707

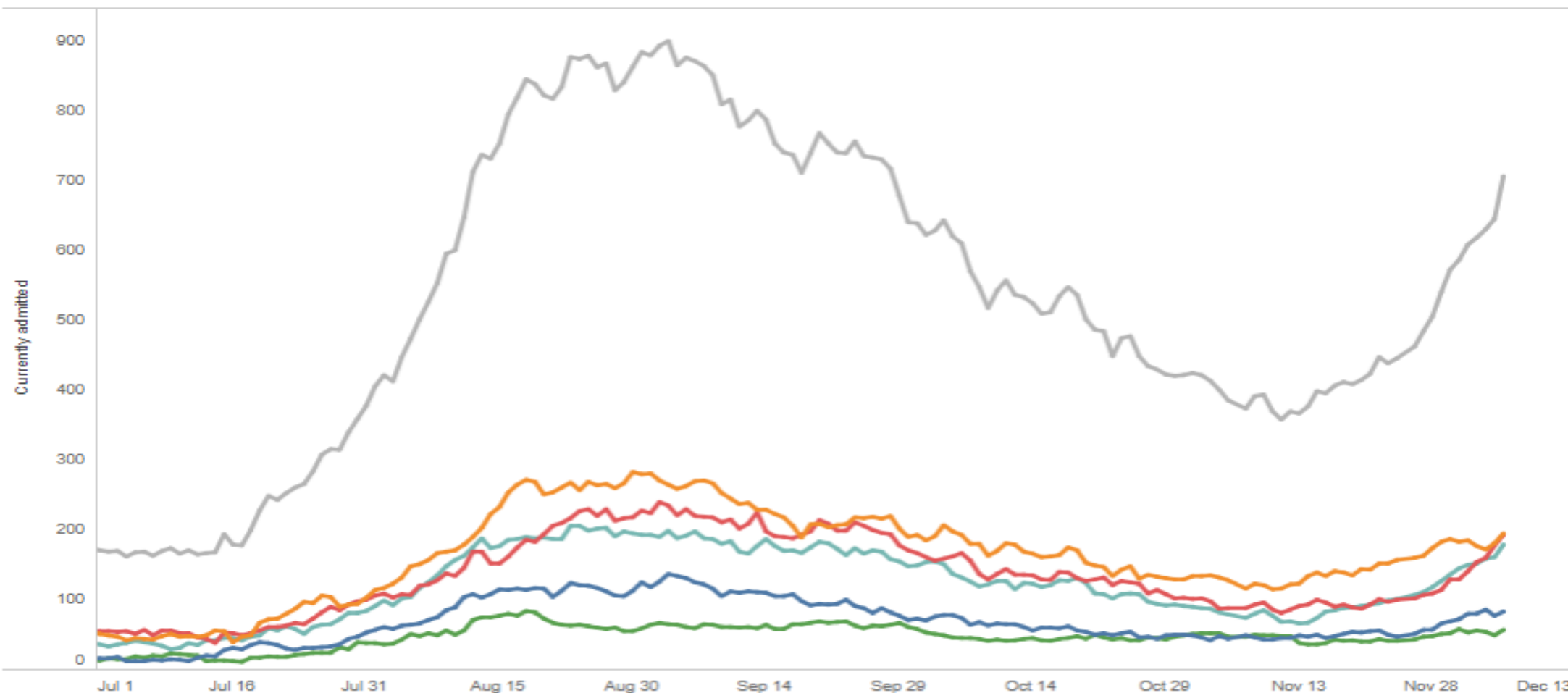
Bronx: 83

Brooklyn: 195

Manhattan: 193

Queens: 179

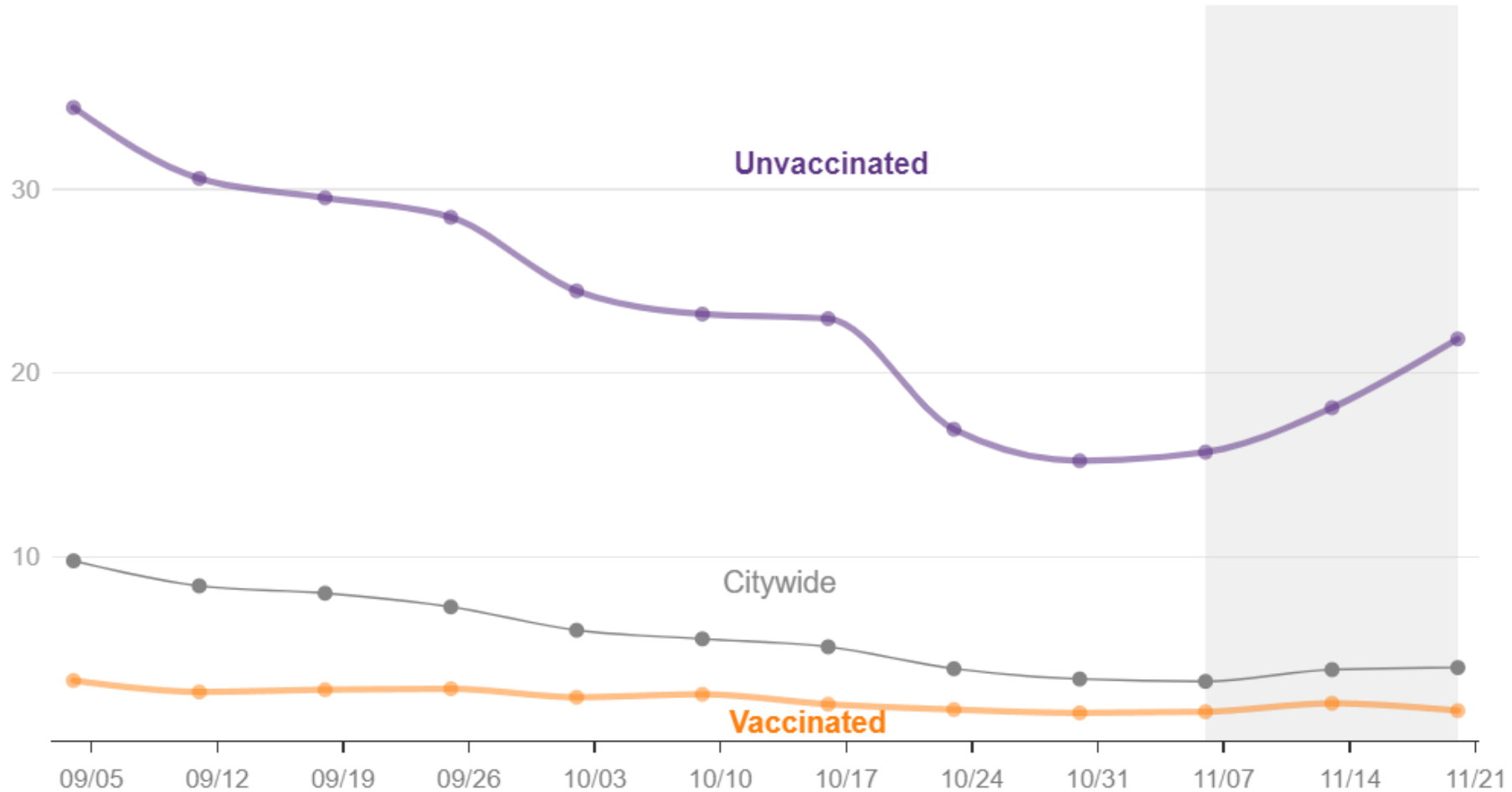
Staten Island: 57



# Weekly Hospitalization Rates by Vaccination Status

Hospitalizations per 100,000 people (age-adjusted, for week ending on listed date)

Recent data may be incomplete.



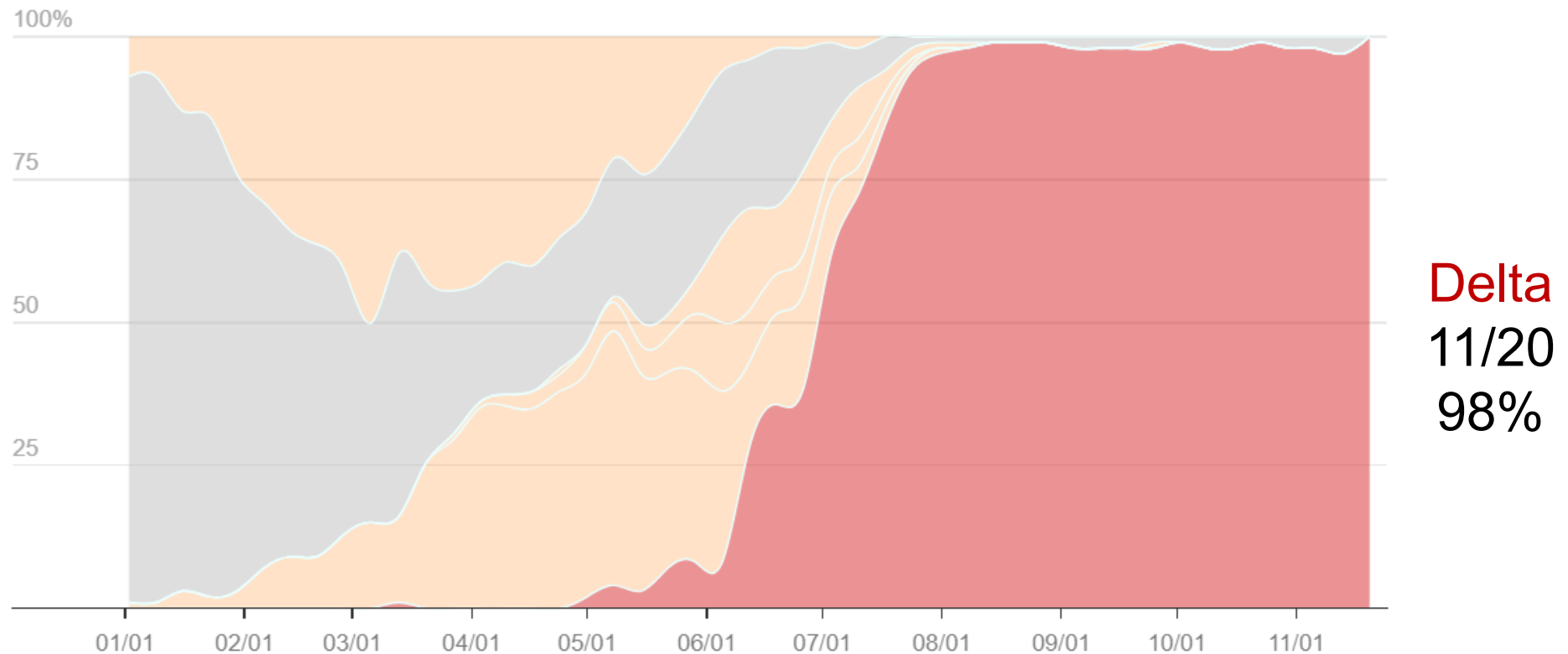
# Spread of Variants in NYC

These charts show the percent and number of tested cases each week that have the four most common variants in New York City: B.1.1.7, B.1.526, P.1 and B.1.617.2.

**Percent** Number

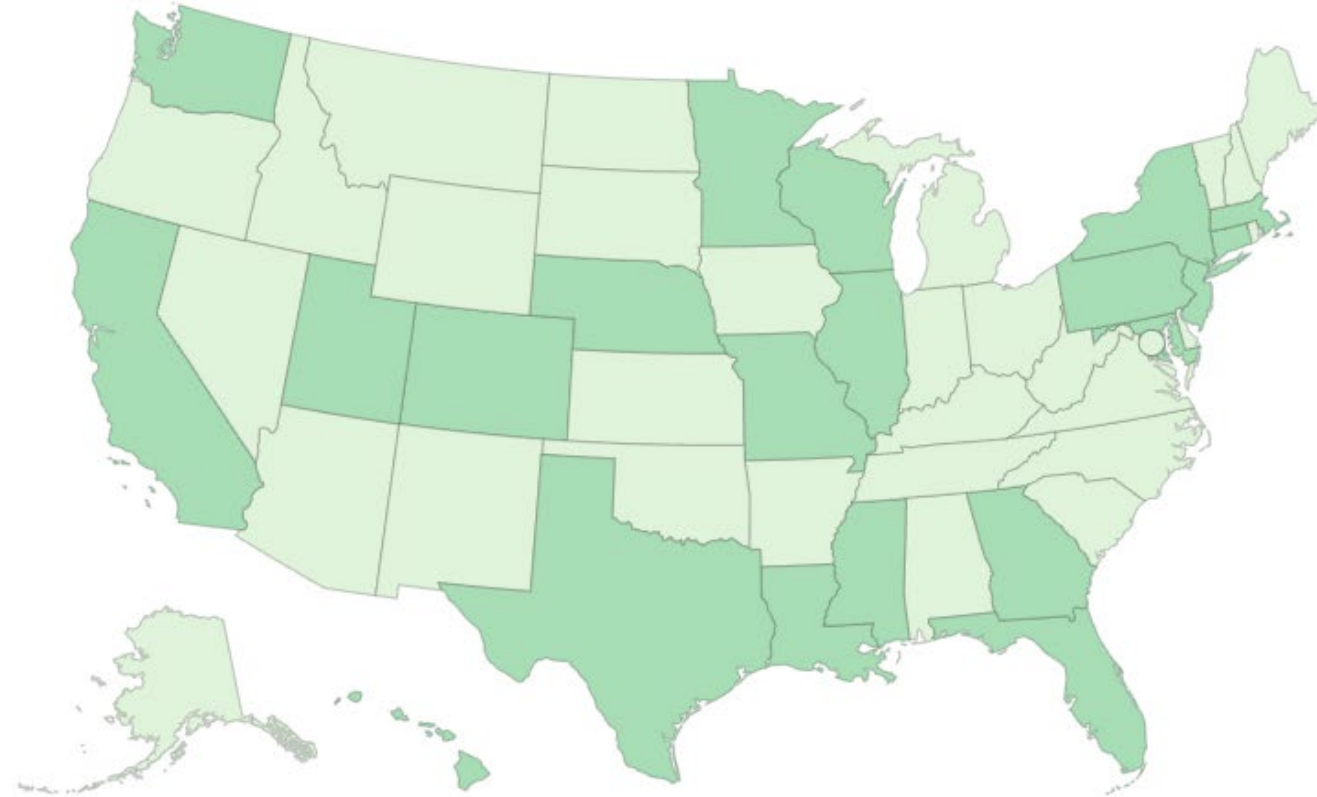
Percent of tested COVID-19 cases with virus variants (for week ending on listed date)

Recent data are incomplete.



## US COVID-19 Cases Caused by the Omicron Variant

Omicron in  
the US and  
NYC



### Legend

- No
- Yes

Territories

- AS
- GU
- PR
- VI
- MP
- FM
- PW
- MH



# Omicron Key Takeaways

- Omicron cases have been detected in New York City, including in people without travel history. New Yorkers should assume that there is community spread of the variant.
  - All New Yorkers should get vaccinated, including a booster, wear a face mask while indoors, and in public and stay home if they have symptoms.
- NYC has one of the strongest variant surveillance systems in the country, sequencing hundreds of cases a week – nearly 15% of samples.
- A lot is still unknown about Omicron – particularly regarding transmissibility, severity, and immunity - studies are underway, and we will know more about the variant in the coming weeks.

# SARS-CoV-2 Variants and Monoclonal Antibodies

- Bamlanivimab + etesevimab
  - Active against Delta (B.1.617.2)
  - **May have significant loss of activity against Omicron**
- Casirivimab + imdevimab (REGEN-COV)
  - Active against Delta
  - **May have significant loss of activity against Omicron**
- Sotrovimab
  - **Likely active against all variants of concern including Omicron**

<https://www1.nyc.gov/site/doh/covid/covid-19-data-variants.page>

# Therapeutic Updates

Under investigation or authorized



# NYC Health Department Focus

- **Despite vaccination, anticipate mAbs/therapeutics will remain an important tool**
  - Significant portion of population may remain unvaccinated
  - Emerging variants
  - Waning vaccine induced immunity
  - Relaxing restrictions and future waves
- **Focused on equitably addressing barriers in the treatment cascade**



# mAbs Updates

12/3/2021: Bamlanivimab and etesevimab EUA expanded to include

- Treatment of mild to moderate COVID-19 in **all younger pediatric patients, including newborns**, who have a positive COVID-19 test and are at high risk for progression to severe COVID-19 and
- Post-exposure prophylaxis for prevention of COVID-19 in all pediatric patients, including newborns, at high risk of progression to severe COVID-19, including hospitalization or death.
- Can be used as treatment in hospitalized patients ages 2 years and younger

[FDA Press Release, 12/3](#)

## **FDA Authorizes New Long-Acting Monoclonal Antibodies for Pre-exposure Prevention of COVID-19 in Certain Individuals.**

- **Evusheld (AstraZeneca)** – Combination of two long-acting mAbs
- Given by IM injection about every 6 six months
- High-risk patients 12 years and older
- Reduced risk of symptomatic COVID-19 by 77%

# Upcoming Therapeutics

- Two oral antivirals being reviewed by FDA for treatment of high-risk adults
  1. **Molnupiravir** (Merck)
    - Reduced risk of hospitalization by 30%
  2. **Paxlovid** (Pfizer)
    - Reduced risk of hospitalization by  $\geq 85\%$
- Both would be taken twice daily x 5 days

# Distribution of New Therapeutics

- EUA for **Evusheld** granted on 12/8/2021
- Expecting EUA for **molnupiravir** and/or **Paxlovid** by end of December
- Initial supplies have been purchased by U.S. Government
  - Will be provided to States/treatment sites for free
- Initial allocations to states will be limited
  - Focus will be on ensuring *equitable* access for *highest risk* patients most likely to benefit

# Conclusion

- Cases and hospitalizations are rising in NYC, especially in unvaccinated New Yorkers
- Omicron is circulating in NY; still many unknowns regarding transmissibility, severity, and immunity
- COVID-19 therapeutics are an essential tool to prevent infection (PEP) and progression to severe COVID-19 in high-risk outpatients
  - **But are not a substitute for vaccination**
  - Important to ensure access for communities most impacted by COVID-19
  - **Timing is key**—the earlier treatments are given, the better it prevents disease progression, hospitalization and death

# Additional Resources

- NYC Health Department's [COVID-19 Outpatient Therapeutics: Information for Providers](#)
  - [Patient handout](#), available in multiple languages
- [HHS Combat COVID-19: Treatment Resources for Clinicians](#)
- [HHS COVID-19 Monoclonal Antibody Therapeutics Digital Toolkit](#)
- New York State: [Ordering COVID-19 Monoclonal Antibody Therapeutics: Information for Providers](#)
- [NIH COVID-19 Treatment Guidelines](#)
- [Infectious Diseases Society of America \(IDSA\) COVID-19 Treatment Guidelines](#)

# Questions?





# Molnupiravir

- **Phase 3 placebo-controlled clinical trial, interim analysis (N=775)**
  - High-risk, non-hospitalized adults, mild to moderate symptoms
  - Symptom onset within 5 days
  - Excluded pregnancy, verified by a negative pregnancy test

	N	Hospitalized or Death (D#29)	Percent Reduction
<b>Molnupiravir</b> bid x 5d	709	48 (6.8%)	30% (p=0.0218)
<b>Placebo</b>	699	68 (9.7%)	

- Efficacy against variants Gamma, Delta, Mu (40% of cases sequenced)
- Adverse event similar between treatment and placebo group

# Paxlovid (PF-07321332; ritonavir)

- **Phase 2/3 placebo-controlled clinical trial, interim analysis (N=1,219)**
- High-risk, non-hospitalized adults, mild to moderate symptoms for  $\leq 5$  days
- Primary endpoint: hospitalization or death

	N	Hospitalized (D#28)	Death	% Reduction
<b>Fluvoxamine</b> bid x 5d	607	6 (1%)	0	85% ( $p < 0.0001$ )
<b>Placebo</b>	612	41 (6.7%)	10 (1.6%)	

- **Subgroup analysis of patients treated within 3 days of Sx onset = 89%**
- Adverse events similar between treatment and placebo group, fewer emergent events in treatment group (1.7% vs. 6.6%)

# Pre-Exposure Prophylaxis (PrEP)

**AZD7442 (AstraZeneca)** – Combination of two long-acting mAbs

- Given by IM injection about every 6 six months
- Phase 3 randomized (2:1), placebo-controlled trial evaluating for the prevention of COVID-19
- 5,197 unvaccinated adult patients with neg SARS-CoV-2 at baseline; 75% with co-morbidities
- Primary endpoint: first case of any PCR positive *symptomatic* illness post dose (prior to day 183)
- AZD7442 group with relative risk **reduction of symptomatic COVID-19 by 77%** (95% CI: 46, 90)

[AstraZeneca Press Release, 8/20/21](#)



# Closing Remarks

David Miller Jr., Executive Director  
Healthcare System Readiness, OEPR-Bureau of Healthcare and  
Community Readiness, NYC DOHMH



**Adjourn**