Centers for Disease Control and Prevention
National Center for Immunization and Respiratory Diseases

Maternal RSV Vaccine Implementation Considerations

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Maternal RSV Implementation Considerations

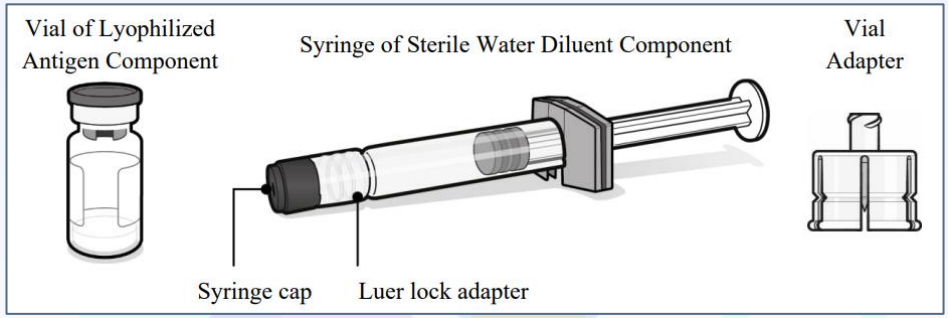
- Vaccine storage, handling, and administration
- Cost of vaccine
- Insurance coverage
- Supply and availability
- Complexity of immunization schedule
- Vaccine demand and coverage in pregnant people
- Obstetric and pediatric provider roles in vaccination decisions
- Immunization information systems
- Communication challenges

Pfizer RSV Vaccine Storage, Handling, and Administration

- Overall clinical implementation similar to other vaccines
  - Stored at 2◦ to 8◦ C
  - Administered as a single dose through intramuscular route

- Additional steps required for dilution, including reconstitution of the lyophilized antigen component with the sterile water diluent component

Supplied as a kit with the following components:



- Proposed recommendations to ACIP allow for simultaneous administration with other recommended vaccines

- Increasing number of vaccines could lead to concerns for limited storage space

Package Insert - ABRYSVO (STN 125769/26) | FDA

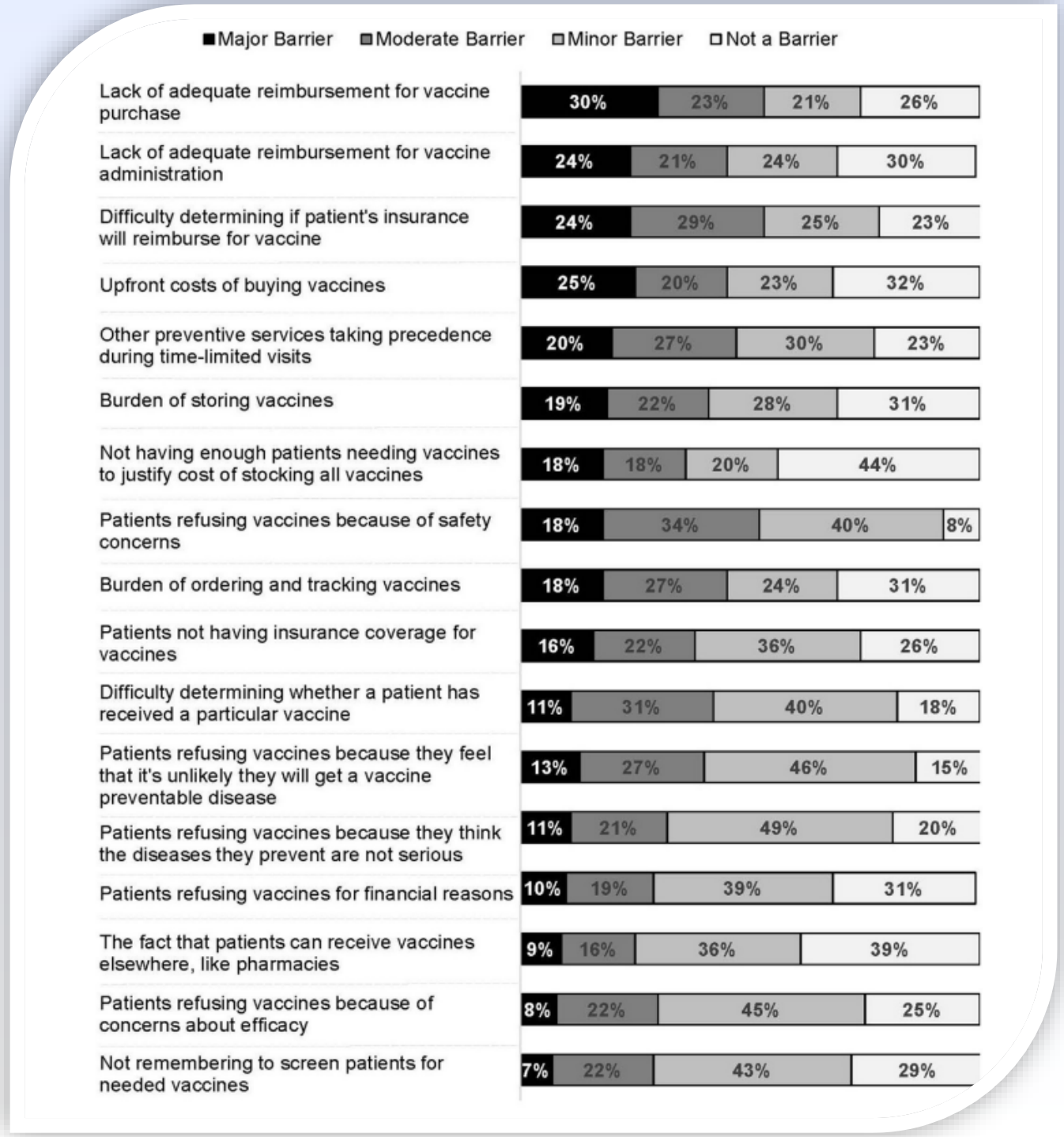
Cost of Maternal RSV Vaccine

- Cost of the Pfizer RSV vaccine is $295/dose, compared to ~$46-52 for Tdap[1]
  - Cost is lower than infant nirsevimab ($495 private sector cost)

- Reimbursement and cost recovery challenges already identified by providers and practices as an implementation barrier for maternal immunization[2]

1. Current CDC Vaccine Price List | CDC
2. Immunization Practices of U.S. Obstetrician/Gynecologists for Pregnant Patients | ScienceDirect

Provider Financial Concerns are a Leading Barrier to Maternal Immunization



Immunization Practices of U.S. Obstetrician/Gynecologists for Pregnant Patients | ScienceDirect

Insurance Coverage of Maternal RSV Vaccine

- Private insurance: **52%** of pregnant people[1]
  - The Affordable Care Act (ACA) requires insurers to cover all ACIP-routinely recommended immunizations for plan years that begin on or after the date that is one year after the date of the recommendation[2]

- Medicaid: **41%** of pregnant people[1]
  - After 10/1/23, when the Inflation Reduction Act provisions become effective, state Medicaid agencies will be required to cover vaccines and their administration without cost-sharing for nearly all full-benefit adult beneficiaries covered under traditional Medicaid, if the CDC/ACIP recommendations apply[3]

- No insurance: **4%** of pregnant people "self-pay" (likely uninsured)[1]
  - If recommended, ACIP will vote on a Vaccines for Children resolution for maternal RSV vaccine in people aged <19 years
  - For people age 19+ years, limited availability (e.g., through 317 program)

1. Products - Data Briefs - Number 468 - May 2023 (cdc.gov); insurance status refers to source of payment for delivery. Another ~3% used other types of coverage
2. 42 U.S. Code § 300gg–13 - Coverage of preventive health services | Cornell Law School
3. Anniversary of the Inflation Reduction Act: Update on CMS Implementation | CMS

Insurance Coverage for Infant Nirsevimab

- ACIP has recommended nirsevimab as a routine immunization. Therefore, it will be covered under the ACA without cost sharing by the patient starting in the effective plan year[1]

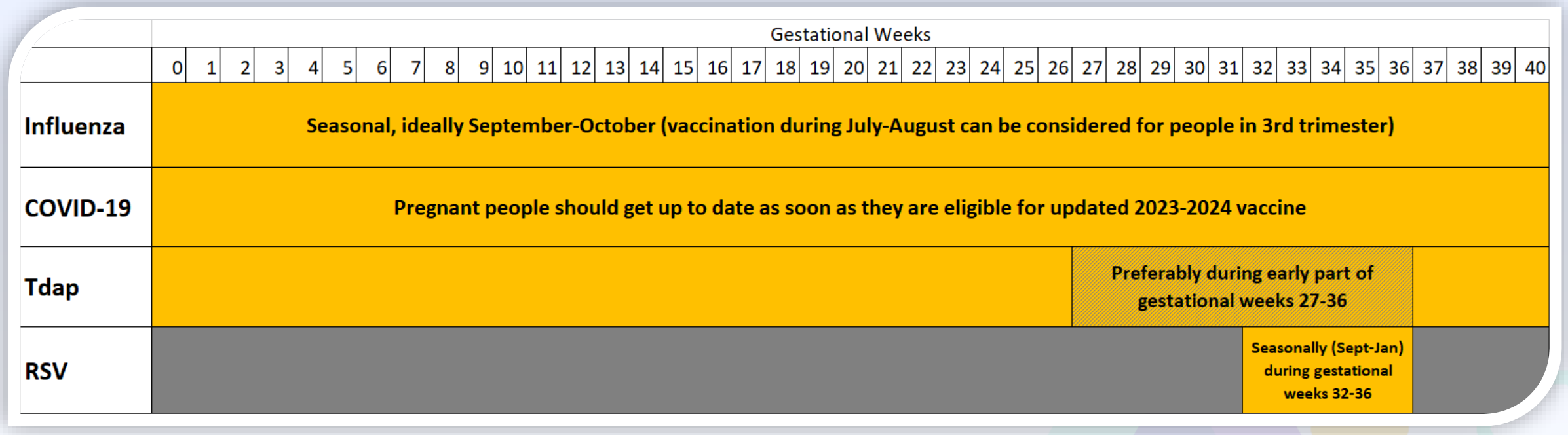
- Nirsevimab is included in the Vaccines for Children Program[2]
  - Eligible children (~50% of U.S. children) will be able to access nirsevimab at no cost

1. 42 U.S. Code § 300gg–13 - Coverage of preventive health services | Cornell Law School
2. Advisory Committee on Immunization Practices, Vaccines for Children Program | CDC

Supply and Availability of Maternal RSV Vaccine and Nirsevimab During 2023–2024 RSV Season

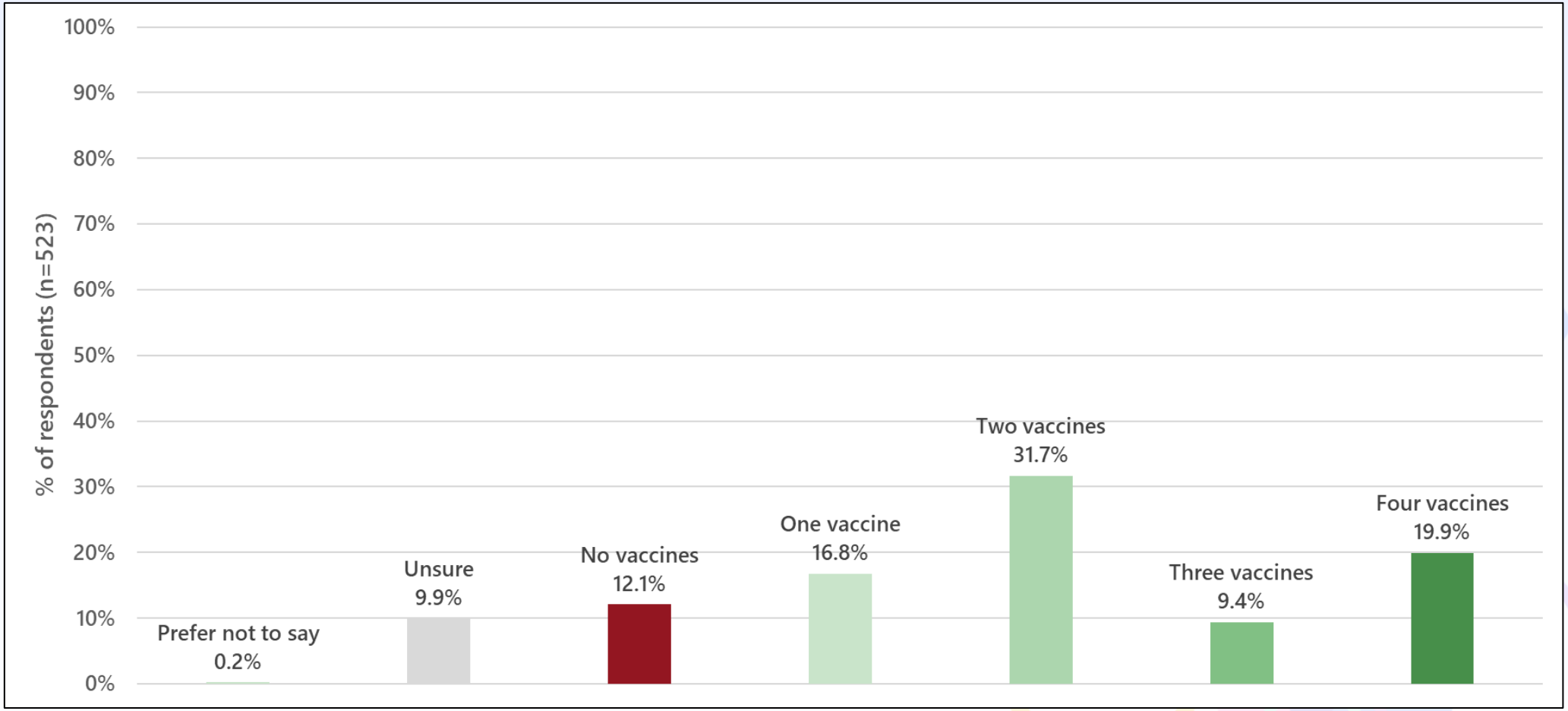
- No anticipated supply/demand mismatch
- Because the Pfizer maternal RSV vaccine is the same product in use for adults aged ≥60 years, availability is expected shortly after ACIP recommendations
- Nirsevimab will likely be available late September/early October, but may not be available in all pediatric settings this season
  - Efforts underway to increase number of birthing hospitals who will administer nirsevimab

Increasing Complexity of Maternal Immunization Schedule



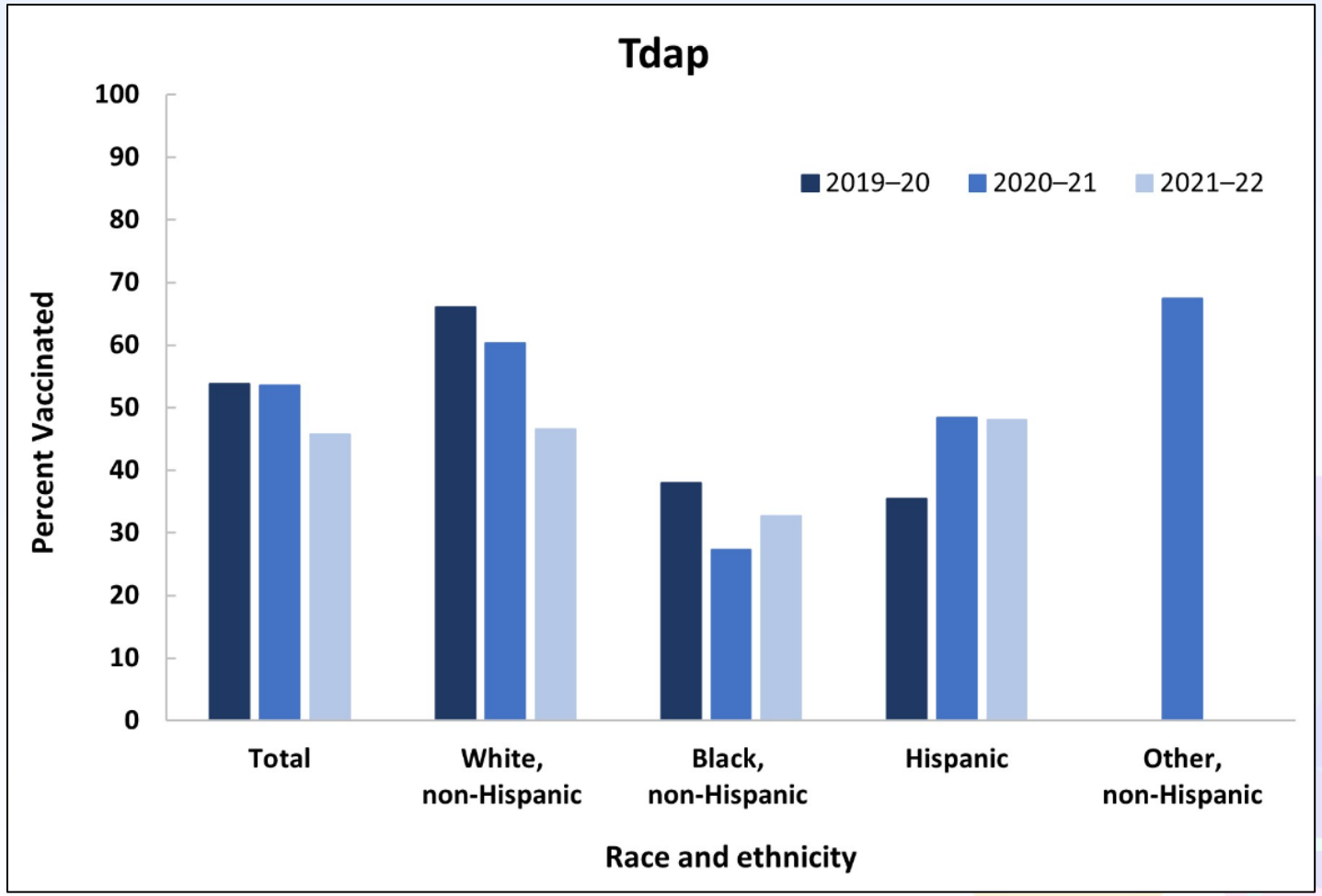
- Increasingly complex maternal immunization schedule, with different timing of vaccines based on season and/or gestational age (with seasonal timing varying in some locations)
- Limited window for RSV vaccine administration
- Unclear willingness of pregnant people to accept multiple vaccines in pregnancy

In a survey of pregnant people, 12% said they would accept no vaccines, and 49% said they would accept 1-2 vaccines



CDC and University of Iowa/RAND survey, unpublished

Uptake of Vaccines among Pregnant People Has Declined and Disparities Persist



Flu, Tdap, and COVID-19 Vaccination Coverage Among Pregnant Women – United States, April 2022 | CDC

Obstetric Provider Role in Immunization Decisions

- Decisions for whether to administer maternal RSV vaccine or infant nirsevimab will need to be made during pregnancy
- Studies continue to demonstrate healthcare providers as pregnant people's most trusted source of information on vaccines, and provider recommendation is a strong predictor of vaccination[1]
- However, one survey showed that 2/3 of obstetricians did not feel providing information about routine childhood immunizations was part of their role[2]

1. Lutz C, et al. Understanding barriers and predictors of maternal immunization: Identifying gaps through an exploratory literature review. Vaccine 36 (2018): 7445-7455
2. Missed Opportunities: A National Survey of Obstetricians About Attitudes on Maternal and Infant Immunization | SpringerLink

Pediatric Provider Role in Immunization Decisions

- Recommendations for nirsevimab that are contingent upon knowledge of maternal vaccination status could be challenging if the pediatric provider does not receive the maternal record

- Verbal report of vaccines received during pregnancy may not be reliable[1]

- Pediatric providers may need to make decisions on nirsevimab administration with incomplete information on maternal vaccination status

1. Tdap Vaccination Coverage During Pregnancy — Selected Sites, United States, 2006–2015 | CDC

Immunization Information Systems (IIS)

- State IIS vary in adult immunization capture

- Pregnancy status not identified in IIS, though could potentially consider RSV vaccine administrations in adult women (<age 60 years) as a proxy

- Unable to link maternal and infant immunization records in the IIS
  - Clinical Decision Support for immunization unable to take into account maternal vaccination history for forecasting for infant nirsevimab immunization
  - Some state IIS policies limit ability of pediatric providers to review adult records, or records for individuals who are not their patients

Communications Challenges

- Terminology: Vaccine (maternal product) vs. Immunization (infant product)

- Conveying potential risks and benefits of each approach, and helping the pregnant person make an informed decision
  - Including potential but undetermined risk of preterm birth with maternal immunization

- Discussing financial implications to patient in setting of uncertainties about coverage during the first year of implementation

Communications Activities

- Formative Research and Message Testing:
  - Focus groups and in-depth interviews with pregnant people and prenatal health providers (in progress)
  - Surveys with parents of young children and pregnant and recently pregnant people
- Patient and provider education materials
- Digital partnerships with healthcare provider organizations
- Partnerships with organizations that serve pregnant people
- Social media across CDC's platforms

Thank You