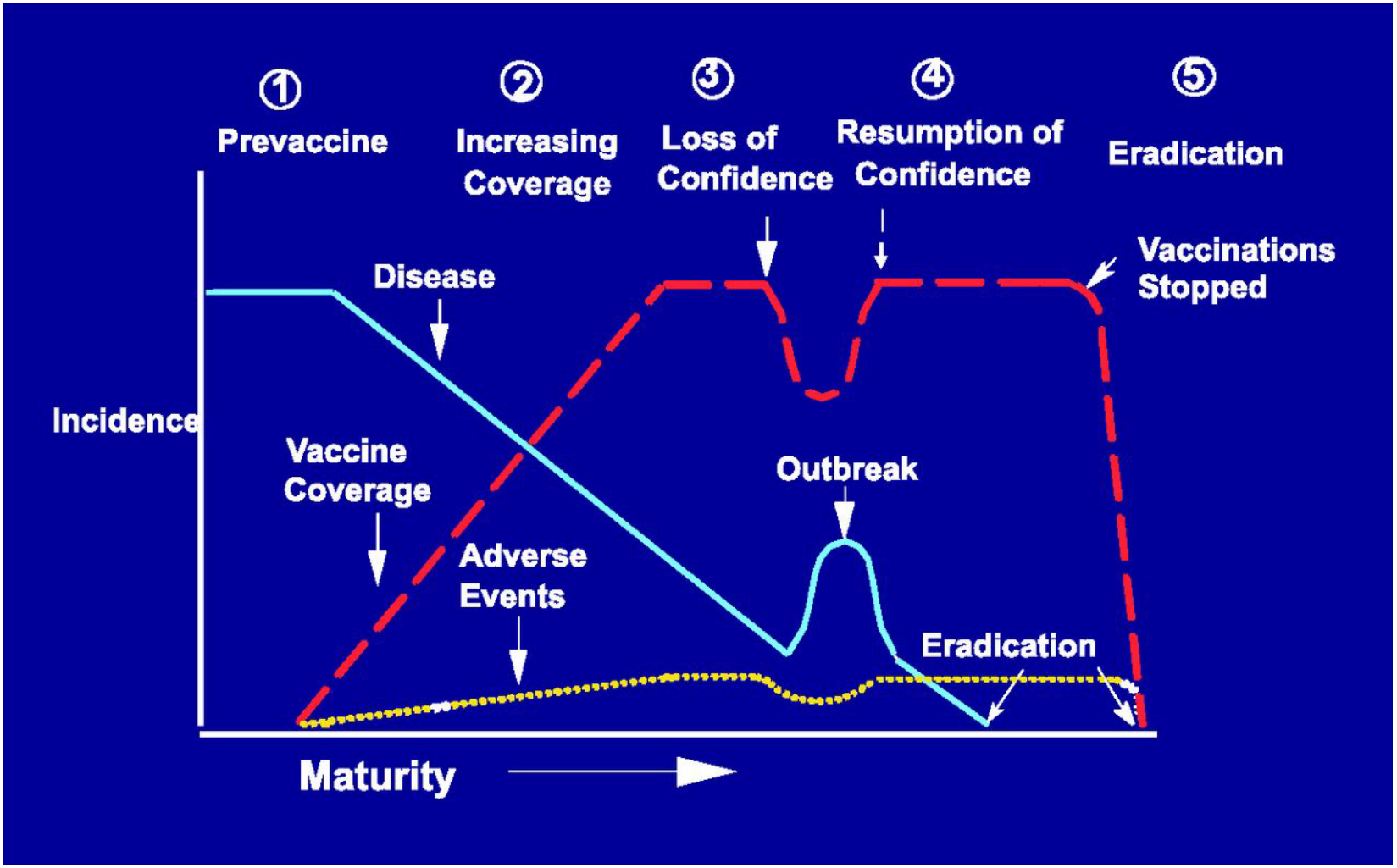
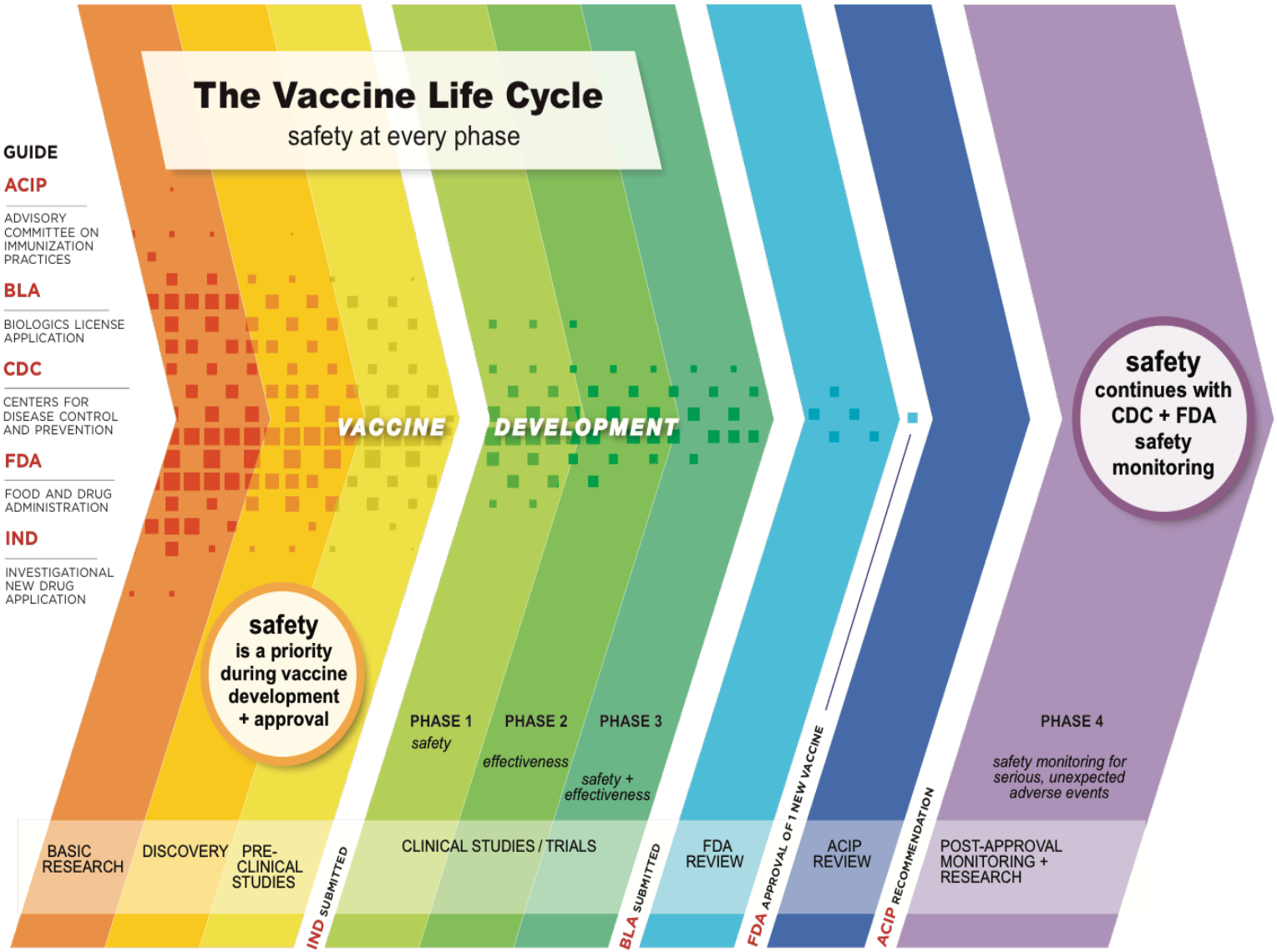
Additional Workgroup Considerations in COVID-19 Vaccination Policy and Practice

Simple, stable recommendations can increase vaccine coverage



Evolution of a vaccine program. Chen RT, Orenstein WA. Epidemiologic methods in immunization programs. Epidemiol Rev. 1996;18(2):102. Copyright © 1996 by the Oxford University Press.

Edwards K, Hackell J, Committee on Infectious Diseases, Committee on Practice and Ambulatory Medicine
Pediatrics Sep 2016, 138 (3) e20162146; DOI: 10.1542/peds.2016-2146



LEARN MORE

FDA VACCINE DEVELOPMENT + APPROVAL PROCESS http://go.usa.gov/xvvNd

CDC VACCINE SAFETY MONITORING + RESEARCH http://go.usa.gov/xvvNe

CDC's Immunization Safety Office Monitors Vaccine Safety Through Strong, Complementary Systems

VAERS	VSD	CISA Project	V-safe
			
1990	*1990*	*2001*	*2020*

Systems work together to rapidly detect and assess potential safety concerns to help inform public health actions

VAERS does not identify causality; rather it is a signal detection tool

CDC's Comprehensive Approach to Studying COVID-19 Vaccine Safety

Surveillance
Analyze spontaneously reported events

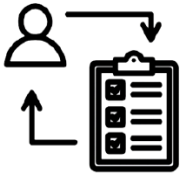
Epidemiologic studies
Assess specific safety questions

Clinical Research
Safety studies to guide clinical practice

Pregnancy Registry
Longitudinal assessment of maternal and infant outcomes

Rapid cycle analyses
Quickly detect potential concerns for investigation

Data mining
Assess >60,000 outcomes for unexpected events



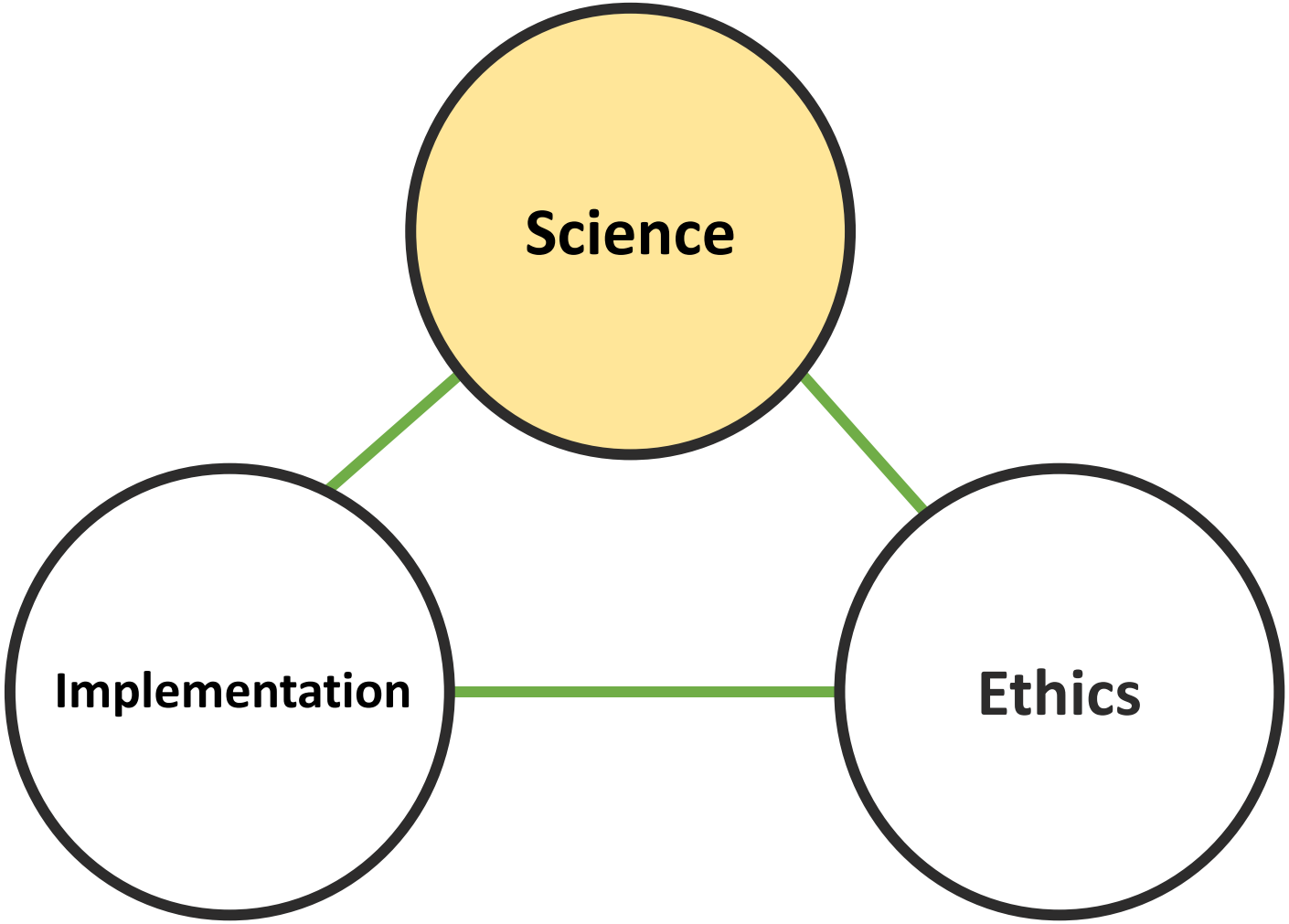
Patient surveys
Assess symptoms and health impacts

Effectiveness of COVID-19 vaccination

- Vaccination provided **additional protection** against COVID-19-associated:
  - ✓ER and UC visits among children; protection generally similar across age groups
  - ✓ER and UC visits and hospitalizations compared to no vaccine dose among adults
  - ✓critical illness among older adults; protection appeared to be more durable against critical illness compared to less severe outcomes

- VE should be interpreted as the added benefit of COVID-19 vaccination in a population with high levels of infection-induced immunity, vaccine-induced immunity, or both

Three Pillars of the ACIP: Science and Much More

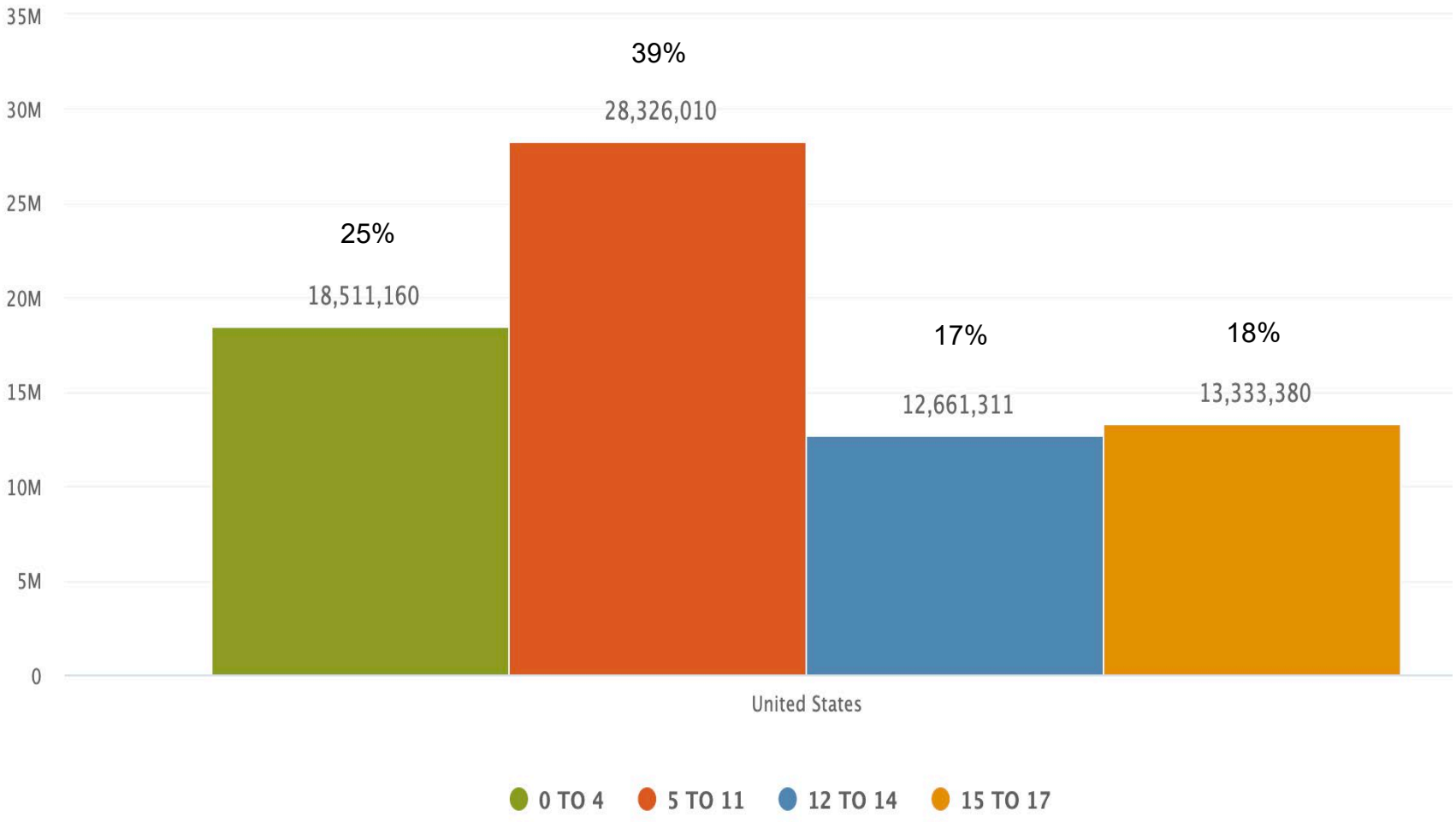


Lee G, Bell B, Romero J. The Advisory Committee on Immunization Practices and Its Role in the Pandemic Vaccine Response. JAMA Published Online July 22, 2020. doi:10.1001/jama.2020.13167

Shared clinical decision-making (SCDM) and a need for provider prescription create barriers to COVID-19 vaccination

- Healthcare providers always discuss vaccination pros/cons with patients.
- In principle, clear recommendations and SCDM reach the same goal.
- **With routine, age- or risk-based recommendations, the default decision is to vaccinate all patients that consent**
- **However, recommendations with SCDM are perceived differently.**
  - ✓SCDM has no default – vaccination is often interpreted as optional
- Plus, the need for a provider prescription creates an unnecessary step to receiving a vaccine and does not effectively target those at high risk

2023 CHILD POPULATION BY AGE GROUP IN US
(CHILDREN < 5 MORE LIKELY TO BE INFECTION NAÏVE)



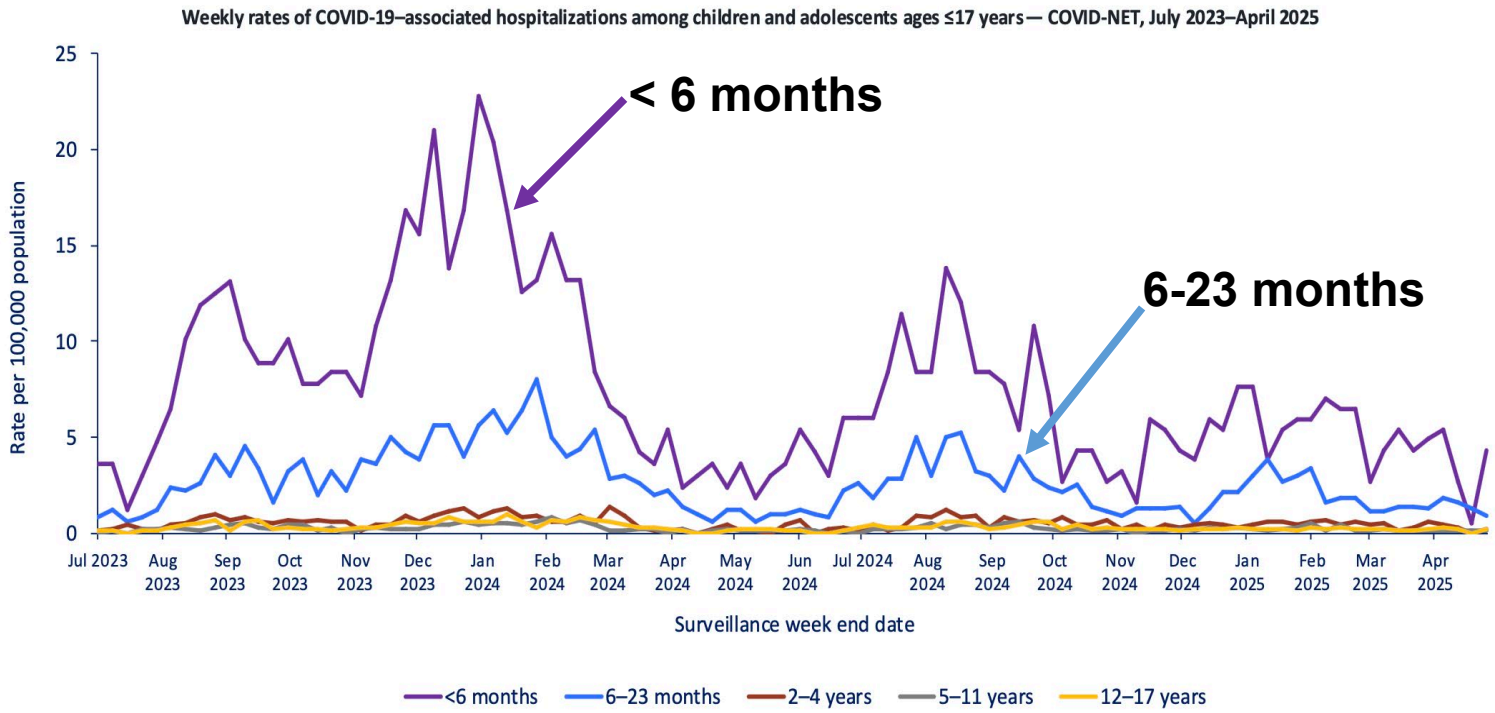
Data from the U.S. Census Bureau, Population Division
Annie E. Casey Foundation tracks the well-being of children, youth, and families in US

COVID-19 Vaccine Safety in Children Ages 6 Months to 11 Years

- Risk of myocarditis following COVID-19 vaccines in children aged <12 years is low, particularly for those aged 6 months to 5 years
  - Active, sequential analyses in the Vaccine Safety Datalink have demonstrated no statistical signals for myocarditis in children
  - No confirmed myocarditis cases in children aged <5 years in VAERS or VSD
- Rapid cycle analyses in the VSD demonstrate no increased risks for 22 other pre-specified outcomes following COVID-19 vaccination
- Evaluations to assess multisystem inflammatory syndrome in children (MIS-C) following COVID-19 vaccination demonstrated that most patients had evidence of preceding SARS-CoV-2 infection

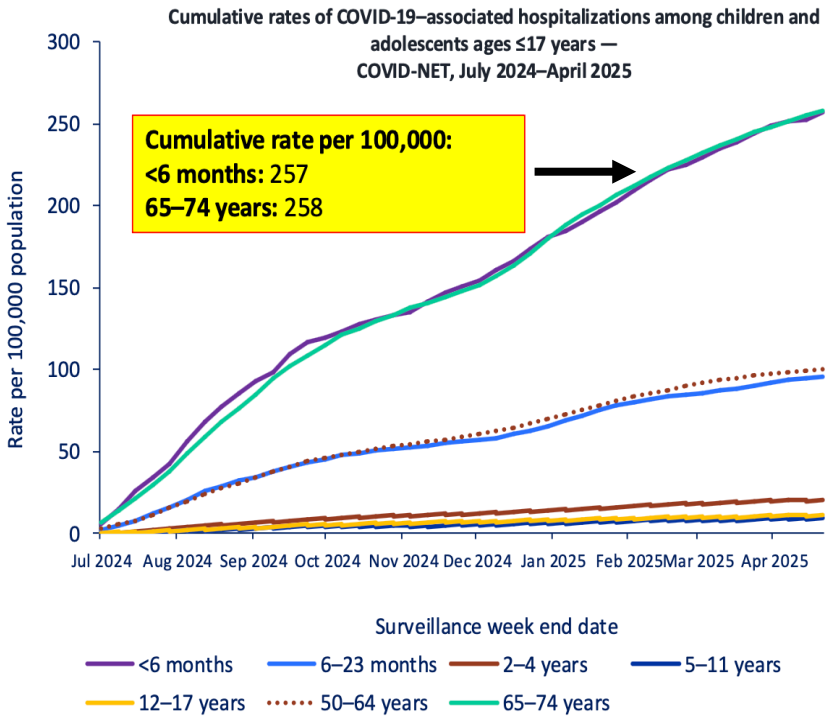
Safety of COVID-19 Vaccination in United States Children Ages 5 to 11 Years | Pediatrics | American Academy of Pediatrics; Safety Monitoring of mRNA COVID-19 Vaccine Third Doses Among Children Aged 6 Months–5 Years — United States, June 17, 2022–May 7, 2023 | MMWR; COVID-19 Vaccine Safety First Year Findings in Adolescents | Pediatrics | American Academy of Pediatrics; Safety Monitoring of Bivalent COVID-19 mRNA Vaccine Booster Doses Among Children Aged 5–11 Years — United States, October 12–January 1, 2023 | MMWR; COVID-19 mRNA Vaccine Safety Among Children Aged 6 Months–5 Years — United States, June 18, 2022–August 21, 2022 | MMWR; Safety of COVID-19 mRNA Vaccination Among Young Children in the Vaccine Safety Datalink | Pediatrics | American Academy of Pediatrics; Surveillance for Multisystem Inflammatory Syndrome in US Children Aged 5-11 Years Who Received Pfizer-BioNTech COVID-19 Vaccine, November 2021 through March 2022 – PubMed; Reported cases of multisystem inflammatory syndrome in children aged 12–20 years in the USA who received a COVID-19 vaccine, December, 2020, through August, 2021: a surveillance investigation - The Lancet Child & Adolescent Health

Among all children and adolescents, rates of COVID-19–associated hospitalizations are highest among infants and children ages <2 years.



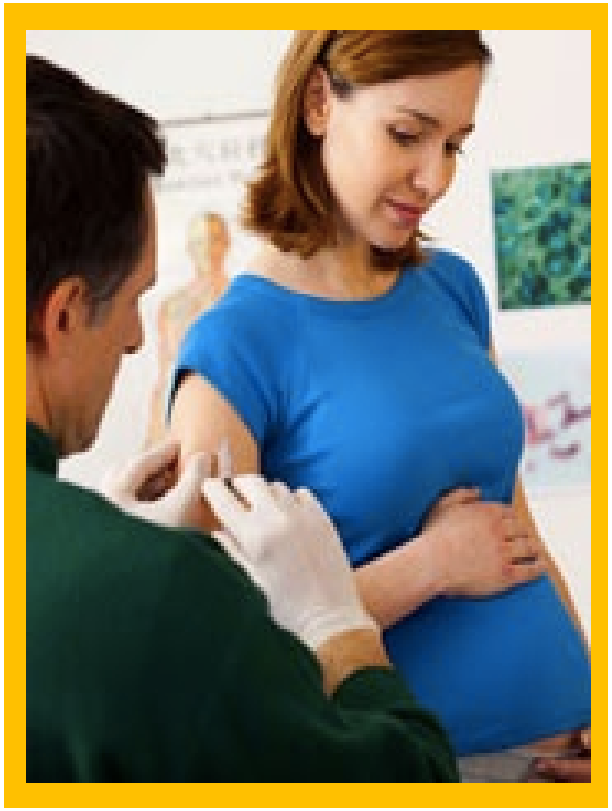
COVID-19 causes severe disease in infants <6 months.

- **Highest rate of COVID-19-associated hospitalization among all pediatric age groups**
  - Rates comparable to adults ages 65–74 years



Data reported from April 2024–March 2025. Excludes newborns who were admitted during the same hospitalizations as their birth.

Antepartum Vaccination Protects Newborns and Young Infants



COVID-19 Vaccine Safety During Pregnancy

Across CDC studies, evidence shows NO increased risk of:

Maternal outcomes

- 25 medically-attended adverse events
- Serious adverse events
- Pregnancy-related conditions
- Maternal ICU admission

Pregnancy outcomes

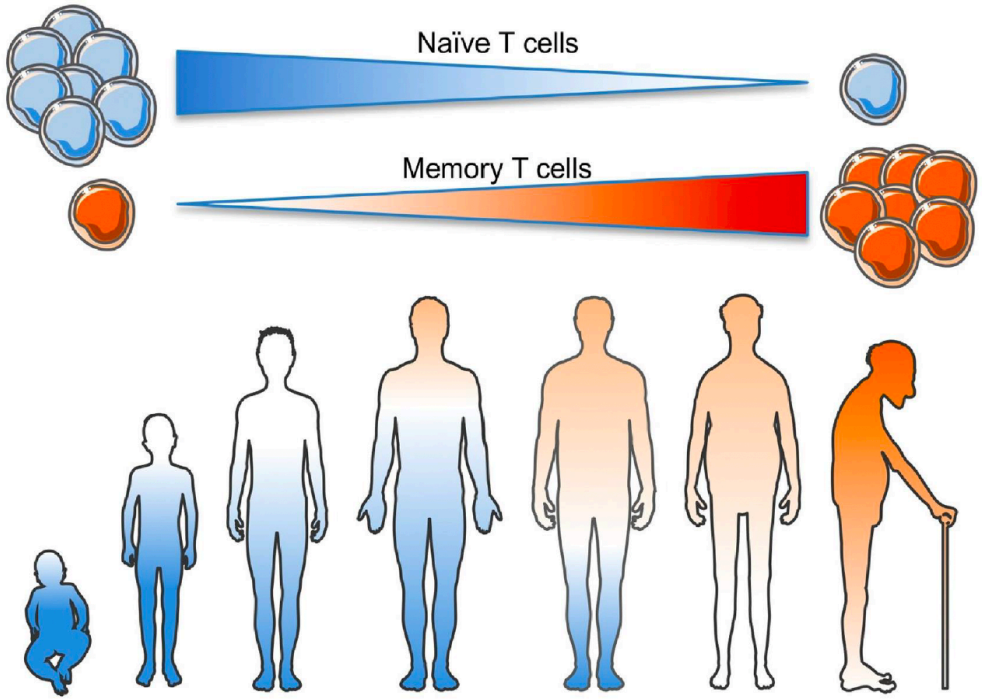
- Miscarriage
- Stillbirth
- Preterm birth
- Small-for-gestational age

Infant outcomes

- Major birth defects
- Neonatal ICU admission
- Infant death

Evaluation of Acute Adverse Events after Covid-19 Vaccination during Pregnancy | New England Journal of Medicine; Receipt of COVID-19 Vaccine During Pregnancy and Preterm or Small-for-Gestational-Age at Birth — Eight Integrated Health Care Organizations, United States, December 15, 2020–July 22, 2021 | MMWR; Receipt of mRNA Covid-19 Vaccines and Risk of Spontaneous Abortion | New England Journal of Medicine; Spontaneous Abortion Following COVID-19 Vaccination During Pregnancy | Public Health | JAMA | JAMA Network; COVID-19 Booster Vaccination in Early Pregnancy and Surveillance for Spontaneous Abortion; Coronavirus Disease 2019 (COVID-19) Vaccination and Stillbirth in the Vaccine Safety Datalink; Medically Attended Acute Adverse Events in Pregnant Women ; Obstetric Complications and Birth Outcomes After Antenatal Coronavirus Disease 2019 (COVID-19) Vaccination; COVID-19 Vaccination in the First Trimester and Major Structural Birth Defects Among Live Births ; Accumulating Robust Evidence for Reducing Vaccine Hesitancy in Early Pregnancy—Reply

“Immunosenescence” means older people do not have as good an immune response as when younger



Immunosenescence refers to age-associated immune decline that may result in an inefficient immune response to novel antigens and an inability to develop proper immunity against infections and upon vaccination.

Source: de Candia P, Prattichizzo F, Garavelli S, Matarese G. T Cells: Warriors of SARS-CoV-2 Infection. Trends Immunol. 2021 Jan;42(1):18-30. doi: 10.1016/j.it.2020.11.002. Epub 2020 Nov 13. PMID: 33277181; PMCID: PMC7664351

Key Messages for Consideration

- The ACIP pillars are not driven by science alone; implementation and ethics are additional important considerations for vaccine accessibility
- Simple, stable recommendations can increase vaccine coverage
- COVID-19 vaccines are highly safe and effective
- Shared clinical decision-making and the need for a provider prescription create unnecessary steps to receiving a vaccine and do not effectively target those at high risk

Key Messages for Consideration

- COVID-19 vaccination rates in the younger pediatric population are very low: the primary COVID-19 vaccination series is needed
- Antepartum vaccination especially helps protect infection-naïve newborns and young infants under 6 months of age
- Older people do not make as good an immune response as when younger ("Immunosenescence")
- COVID-19 vaccination matters for pregnant women, pediatric patients especially < 2 years of age, people 65 years and older, those of any age with a weakened immune system or chronic medical conditions, and anyone who feels they want protection for themselves or their family!