Introduction to the Cytomegalovirus (CMV) Vaccines Work Group

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Chair, CMV Vaccines Work Group

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Advisory Committee on Immunization Practices

Public Health Problem - CMV

- **Congenital CMV**
  - Most common infectious cause of neurodevelopmental disabilities in U.S. children
  - ~4,000 children with congenital CMV disease each year
- **Persons with immunosuppression**
  - Substantial morbidity and mortality
- **Identified as highest priority for vaccine development in the 21st century**

CMV Vaccine Development

1970s **Towne and AD169 (live attenuated vaccine strains)**

Phase 1: solid organ transplant recipients, CMV-seronegative females

1990s **Glycoprotein B (gB)/MF59 vaccine**

Phase 2: CMV-seronegative females 14-40 years

2010s **V160 vaccine (AD169 + Pentameric Complex)**

Phase 2b: CMV-seronegative females 16-35 years

Earlier vaccine candidates did not progress to phase 3 trials

2020s **ASP0113 (DNA-based, gB + pp65)** → *Failed to achieve efficacy for primary endpoints*

Phase 3: CMV-seropositive allogeneic hematopoietic cell transplant recipients

mRNA-1647 CMV vaccine (gB + Pentameric Complex) → *Ongoing trial with results expected soon*

Phase 3: Females 16-40 years

ACIP CMV Vaccines Work Group Objectives

- Review epidemiology of CMV and congenital CMV
- Identify areas where additional data are needed
- Review safety, immunogenicity, and efficacy data for CMV vaccine candidates
- Develop CMV vaccine policy options

ACIP CMV Vaccines Work Group

Chair

- Denise Jamieson

CDC Co-Leads

- Tatiana Lanzieri
- David Sugerman

Work Group Members

- Pending

ACIP CMV Vaccines Work Group Initial Timeline

- **November 2024 – first work group meeting**
- **February 2025 – presentation at ACIP meeting**
  - Burden of CMV and congenital CMV