

There is no CMV vaccine available to prevent congenital CMV (cytomegalovirus). CMV vaccines are still in the research and development stage, including live vaccines, attenuated vaccines, and subunit vaccines that target individual proteins. Many experts believe that a CMV vaccine could be possible within the next 10 to 20 years, but a CMV vaccine is unlikely to occur without the awareness and support of the general public, the pharmaceutical industry, and the federal government.

CMV VACCINE PROGRESS

There are many pharmaceutical industry-sponsored clinical trials for CMV vaccines, but these focus on other at-risk populations, including HIV patients and organ transplant patients. While important, data from these CMV vaccine trials cannot be applied towards a congenital CMV vaccine.

For a congenital CMV vaccine, there have been approximately 10 phase 1 trials, 2 phase 2 trials, and no phase 3 trials to date. Vaccine clinical trials costs:

- Phase 1 trial - less than \$1 million
- Phase II trial - \$5-\$10 million
- Phase III trial - \$10-\$100 million

ECONOMIC BURDEN/COST IMPACT

In the 1990s, the annual cost for caring for children born with congenital CMV was estimated at \$1-\$2 billion for the United States alone.

There have been no recent studies to re-evaluate the cost impact of congenital CMV.

GOVERNMENT RECOMMENDATIONS

In 1999, the National Institute of Medicine (IOM) reviewed 26 conditions with the potential for vaccine prevention. Each different candidate vaccine was ranked from Levels I-IV (highest to lowest) based on cost impact and Quality of Life Adjusted Year (QALY) saved.

A congenital CMV vaccine, given to 12-year-olds, was ranked the first priority in the Level I group because of cost savings as well as the human suffering that would be alleviated by stopping CMV.

National CMV presented at the first Food and Drug Administration (FDA) and Centers for Disease Control and Prevention (CDC) sponsored CMV Vaccine Workshop. The two-day event brought together many industry representatives and regulators to discuss paths forward to a viable CMV vaccine. National CMV has been active on Capitol Hill, keeping legislators updated on the progress being made towards a CMV vaccine and education policymakers regarding the importance of CMV vaccine development.

