

# IGNITING ADVANCES IN IMMUNIZATION

## Funding Unmet Needs



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# Overview

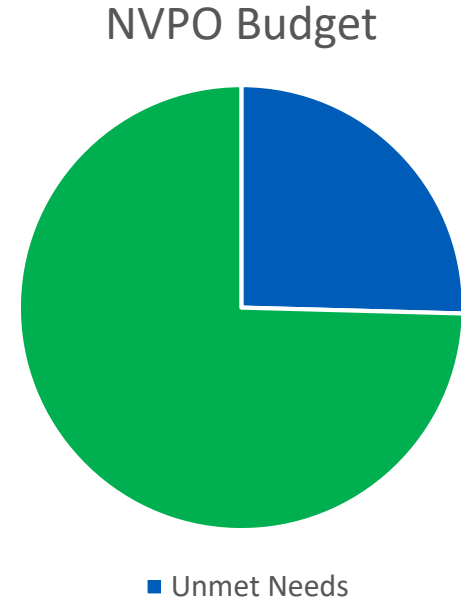
- NVPO Background
- Funding Priorities
- Fiscal Year (FY) 2018 Projects
- Fiscal Year (FY) 2019 Projects

# NVPO Background

- **Statutes**
  - Sections 2101 and 2102 of Title XXI of the 1986 National Childhood Vaccine Injury Act (PL 99-660).
  - 21st Century Cures Act
    - “Encouraging Vaccine Innovation: Promoting the Development of Vaccines that Minimize the Burden of Infectious Diseases in the 21st Century” A Report to Congress

# NVPO Background

- **Unmet needs funding is:**
  - Carried out through partnerships with federal agencies involved in immunization
  - Designed to accelerate innovation and respond to emerging needs or gaps
  - Driven and informed by data
- **Total Funding Level: \$6.4M**
  - **Unmet Needs: \$1.5-1.9M**  
(25% or more of NVPO's budget)



# NVPO Priority Areas for Unmet Needs FY18 and FY19

- **Vaccine Coverage**
  - Racial and ethnic disparities
  - HPV vaccination
- **Vaccine Innovation**
  - Supporting successful vaccine development or implementation

# FY18 Unmet Needs Projects and Status



# FY18 Unmet Needs

- **Total Funding:** \$1.5M
- **Total Projects Funded:** 7
- **Project Topics:**
  - **Vaccination Coverage** (HPV, Adult Disparities)
  - **Vaccine Innovation** (GBS, CMV, Lyme, HAI-related pathogens)
  - **Vaccine Safety**

# FY18 Unmet Needs – Vaccination Coverage

Project	Funding	Agency	Focus	Activities
<b>Human Papillomavirus (HPV)</b>	\$100K	CDC	Accelerate HPV vaccination coverage in the southeastern United States by encouraging coalition networking, practice sharing, idea generation, and problem-solving.	<ul style="list-style-type: none"> <li>• Convene Regional Leadership Summit at University of Alabama at Birmingham for HPV coalitions in AK, AL, GA, KY LA, MS, TN)</li> <li>• Quarterly technical support webinars</li> </ul>
<b>Racial and Ethnic Disparities Among Adults</b>	\$200K	CDC	Improve understanding of racial and ethnic disparities in routinely recommended adult vaccine coverage.	<ul style="list-style-type: none"> <li>• Nationally representative survey of adults with oversampling of racial/ethnic minorities age 19+ with chronic conditions to assess current knowledge, attitudes, and behaviors among adults with chronic health conditions regarding routinely recommended vaccine</li> </ul>



# FY18 Unmet Needs – Vaccine Innovation

Project	Funding	Agency	Focus	Activities
<b>Group B Streptococcus (GBS)</b>	\$250K	CDC	Improve understanding of microbial factors contributing to severe cases of GBS to help accelerate vaccine development	<ul style="list-style-type: none"> <li>Supported CDC efforts to complete whole genomic sequencing (WGS) and automated characterization of ABCs group B streptococci (GBS) isolates collected during 2016-2017 (more than 4,460 isolates).</li> <li>Provided population-based vaccine target distributions and antimicrobial susceptibility profiles to accurately represent invasive GBS strains in the US</li> </ul>
<b>Cytomegalo- lovirus (CMV)</b>	\$450K	CDC	Assess the burden of CMV infection and develop laboratory tests to measure immunological response to CMV and viral infection	<ul style="list-style-type: none"> <li>Enrolled 5 hospitals into the study and established IRB approvals</li> </ul>

# FY18 Unmet Needs – Vaccine Innovation

Project	Funding	Agency	Focus	Activities
Lyme Disease	\$250K	CDC	Improve understanding of high-risk groups who will benefit from new Lyme disease vaccine	<ul style="list-style-type: none"> <li>• Focus groups with consumers</li> <li>• Clinician interviews</li> <li>• Report to guide population-based survey development and inform future communication efforts</li> </ul>
Healthcare Associated Infection (HAI) linked Data Systems	\$250K	CDC	Link surveillance and CMS claims data to identify risk groups and settings where HAI vaccination programs should be focused	<ul style="list-style-type: none"> <li>• Link data on <i>Clostridioides difficile</i> infections (CDI) and <i>Staphylococcus aureus</i> at 8 states to CMS claims data</li> <li>• Analyse data to help quantify potential impact of strategies like vaccination and health care settings where vaccines could be most effectively delivered</li> </ul>

# FY18 Unmet Needs – Vaccine Safety

Project	Funding	Agency	Focus	Activities
Vaccine Safety Surveillance	\$308K	CDC	Update and validate CDC's Vaccine Safety Datalink algorithms for identification of birth defects from ICD-9 to ICD-10 coding	<ul style="list-style-type: none"><li>• Update existing algorithms for use with current ICD-10 coding</li><li>• Validate algorithms</li><li>• Describe background prevalence for a 2-year period following transition to ICD-10 coding</li></ul>

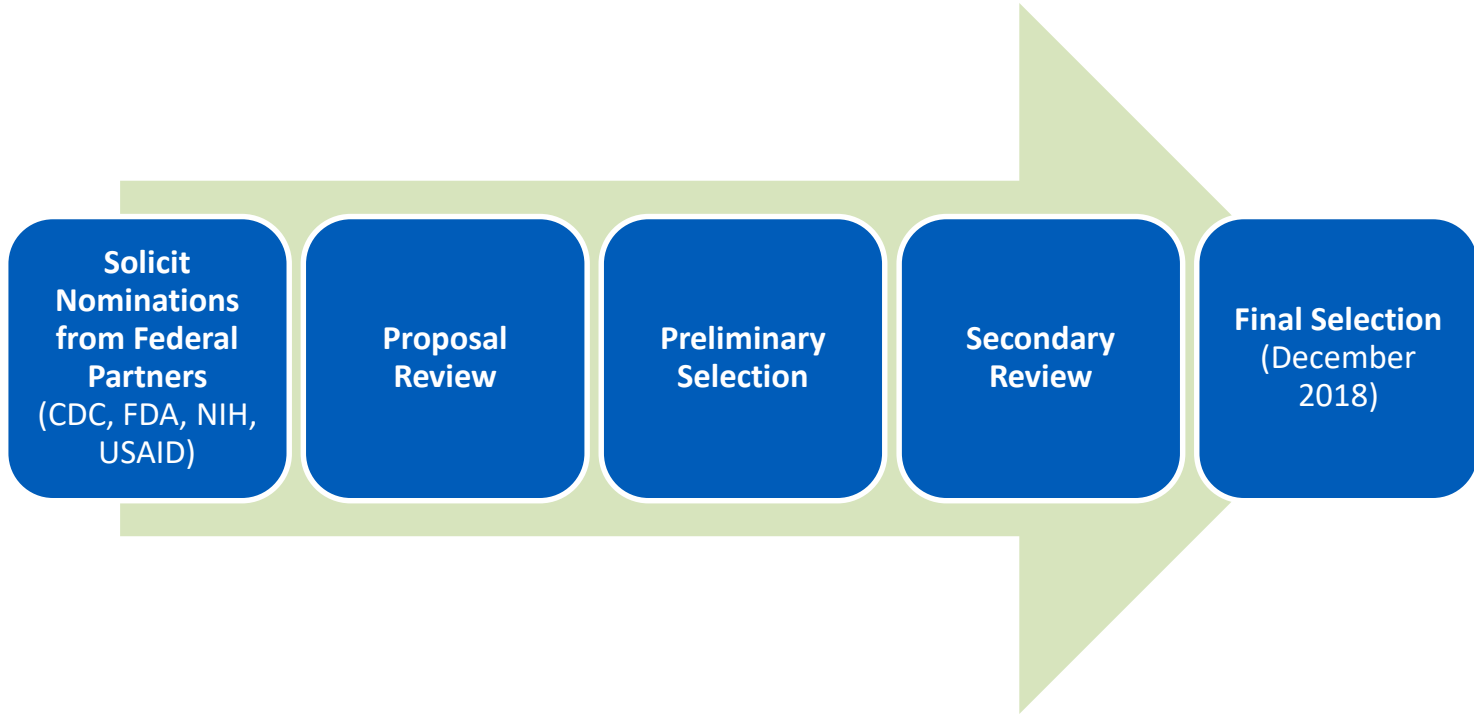
# FY19 Unmet Needs Proposed Projects



# FY19 Unmet Needs

- **Total Funding:** \$1.5-1.8M
- **Total Projects Funded:** 10 preliminary selections currently being considered for funding
- **Project Priorities:**
  - **Vaccination Coverage**
  - **Vaccine Innovation**
  - **Vaccine Safety**

# FY19 Unmet Needs Process



# FY19 Unmet Needs – Vaccination Coverage

Project	Funding	Agency	Focus
Racial/Ethnic Disparities	\$250K	CDC	Link overseas vaccination records of newly arrived refugees between refugee health programs and state Immunization Information Systems (IIS)

# FY19 Unmet Needs – Vaccine Innovation

Project	Funding	Agency	Focus
Polio	\$180K	FDA	Methods for regulatory evaluation of a new generation of polio vaccines
Tuberculosis	\$62K	FDA	Advancing a novel assay to provide a functional correlate of protection that predicts tuberculosis vaccine efficacy
Group A Streptococcal	\$20K	NIH	Consultation meeting to inform development of Group A Streptococcal Vaccine
Pertussis Vaccines	\$20K	NIH	Consultation meeting to inform strategies to overcome waning immunity in pertussis vaccines



# FY19 Unmet Needs – Vaccine Innovation

Project	Funding	Agency	Focus
Cytomegalovirus Vaccines	\$200K	CDC	Improve diagnostic tools for CMV infection
Group A and B Streptococcal Disease	\$368K	CDC	Inform Group A and B Streptococcal vaccine development through characterization of circulating strains and their distribution among different populations
Group B Streptococcal Disease	\$300K	CDC	Inform Group B Streptococcal Vaccine development and support proof of concept towards the establishment of immunologic endpoints for GBS among young infants

**Thank you!**

