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Maternal immunization efforts of the National Institutes of Health

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ABSTRACT

Over the last 35 years, efforts at the National Institutes of Health (NIH) to protect mothers and their infants against infectious diseases have involved a bench-to-bedside approach. Basic and translational research that provided a foundation for clinical trials of vaccines in pregnancy include natural history and vaccine antigen identification studies. Development of laboratory assays and reagents have been funded by NIAID; these are critical for the advancement of vaccine candidates through the preclinical and clinical steps along the maternal immunization research pathway to support vaccine efficacy. Animal models of maternal immunization have been developed to evaluate efficacy of vaccine candidates. Clinical studies required development of maternal immunization protocols to address specific pregnancy related issues, for enrollment and safety assessment of mothers and their infants. NIH has organized and participated in meetings, workshops and other collaborative efforts with partners have advanced maternal immunization efforts. Partners have included many institutes and offices at NIH as well as other Department of Health and Human Services agencies and offices (Food and Drug Administration, Centers for Disease Control and Prevention, National Vaccine Program Office), World Health Organization, academic investigators, Biotech and pharmaceutical companies, and nonprofit organizations such as the Bill and Melinda Gates Foundation. These research and development partnership are essential for advancing maternal immunization. Continued efforts are needed to promote maternal immunization to protect pregnant women and their infants against vaccine-preventable infectious disease, especially in resource-limited settings where the burden of infections is high.

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1. Introduction

Efforts at the National Institutes of Health (NIH) to protect mothers and their infants against infectious diseases have involved a bench-to-bedside approach. Basic and translational research has provided a foundation for clinical studies with investigational and licensed vaccines. These studies assessed the safety and immunogenicity of vaccines in pregnant women and their children. Additional research is ongoing which has the potential to impact maternal immunization by informing policy and product development.

While comprehensive review of each study supported over the past 35 years would have been one approach, the purpose of this review is to highlight several types of nonclinical and clinical studies that led to a better understanding of responses to vaccines administered during pregnancy. Selected NIH supported clinical trials are presented in Table 1.

At the National Institute of Allergy and Infectious Diseases (NIAID) all of the above efforts were funded via grants, contracts and interagency agreements with other government agencies. The breath of the program is demonstrated by diversity of agents and products tested. Studies of vaccines to protect infants against infections caused by *Streptococcus pneumoniae*, group B *Streptococcus* (GBS), *Bordetella pertussis*, *Haemophilus influenzae* type b (Hib), respiratory syncytial virus (RSV), seasonal and pandemic influenza

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Table 1
Selected NIH vaccine studies in pregnant women and their infants.

Vaccine target	Product	Population	Immunogenicity	Persistence of maternal antibodies in infant blood or relevant information if only infant sample was cord blood	Ref.
Group B Streptococcus[a]	GBS III capsular polysaccharide vaccine	40 pregnant women	Immune response rate of 63%, comparable to a study with non- pregnant adults	3 months of age	[5]
	GBS III-TT conjugate	30 pregnant women randomized 2:1 vaccine:saline placebo	Immune response in 95% comparable to non-pregnant women who received same dose and lot of vaccine	2 months of age	[7]
RSV[a]	RSV purified fusion protein-2 (PFP-2) vaccine (Wyeth-Lederle Vaccines)	35 pregnant women randomized 4:3 vaccine:saline placebo	Immune response in vaccine recipients: 75% by Western Blot and 95% by ELISA	2 and 6 months of age	[2]
Pneumo/Hib[a]	*Haemophilus influenzae* type b conjugate (HbOC, HibTITER, Lederle Praxis Laboratories) and 23-valent pneumococcal polysaccharide vaccine (PSV, Pneumovax 23, Merck and Co)	60 pregnant women randomized 2:1 HbOC:PSV	Concentrations of maternal antibody to common pneumococcal serotypes were significantly higher at delivery in PVC immunized mothers versus HbOC immunized mothers	2 and 7 months of age (pneumococcal Ab, varied with serotype) 2 months of age (Hib Ab) Presence of maternally derived anti-PRP did not interfere with the infant's immune response to routine immunization to Hib	[10,11]
Pneumo[a,b]	9 valent pneumococcal conjugate vaccine (PVC-9, Wyeth Lederle)	152 pregnant women randomized 1:1 vaccine:saline placebo	Significantly higher type specific pneumococcal antibodies in mothers receiving PVC-9 compared to controls at delivery and 2, 6 and 13 months post vaccination	Immunization of mothers with PVC-9 correlated with decreased infant antibody responses to some vaccine serotypes (routine immunization with Prevnar)	[35]
Hib[a]	Capsular polysaccharide (PRP) vaccine of *Haemophilus influenzae* tybe b	213 pregnant women randomized to receive PRP or saline placebo Cord samples from 75 deliveries (35 from PRP group and 40 from placebo group)	Infants born to PRP recipients had significantly higher levels of antibody to PRP than infants born to placebo recipients	Estimated that infants of PRP recipients would be protected for average of 4 months compared to two months for infants from placebo controls	[8]
Hib[a]	Hib polysaccharide PRP (HIB-immune, Lederle Labs) Hib conjugate PRP-D (ProHIBiT, Connaught) Hib conjugate HbOC (HibTITER, Lederle Praxis Laboratories)	50 pregnant women randomized to receive PRP [13]; PRP-D [19] and PRP-HbOC [18] 47 unimmunized pregnant women	Mothers who received any Hib vaccine had significantly higher anti-PRP antibodies than unimmunized women. Women who received Hib conjugate vaccines had higher levels than women who receive PRP vaccine.	Protective PRP antibody level in cord specimens from all infants of immunized mothers compared with 60% of unimmunized controls.	[9]
Pertussis[a]	Adacel® (Sanofi Pasteur, Tdap) Tetanus toxoid, reduced diphtheria toxoid and acellular pertussis (Tdap) vaccine	48 pregnant women randomized 2:1, vaccine: saline placebo with crossover immunization postpartum 32 age matched non-pregnant women (Tdap open label)	Significantly higher concentrations of pertussis antibodies at birth and 2 months of age following antepartum versus postpartum vaccination.	2 months of age Pertussis antibody responses in infants born to women receiving Tdap during pregnancy were not different following the fourth dose of DTaP	[20]
Trivalent influenza[a]	Trivalent influenza vaccine (TIV) (Connaught Laboratories) Tetanus toxoid vaccine (TT) (Connaught Laboratories)	30 pregnant women randomized 1:1 TIV:TT	Maternal seroconversion to one or more vaccine antigens in all TIV recipients and 9/13 TT recipients	2 months of age	[36]
Trivalent influenza[c]	Trivalent Influenza vaccines and monovalent H1N1 adminstered as part of routine clinical care	239 pregnant and postpartum women Observational cohort 4 consecutive influenza vaccination seasons	Adequate seroconversion rates demonstrated during pregnancy and postpartum period. Seroconversion rates lowest in first trimester (54.8%) and immediate postpartum (54.8%) and highest in late third trimester (69.6%) and late postpartum (69.4%).	Not applicable as no infant blood samples collected.	[37]

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