

# IMMUNIZATION RULES FOR PREMATURE NEWBORNS

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## Abstract

Immunization of premature newborns is a critical component of neonatal healthcare aimed at protecting this high-risk group from severe infectious diseases. Due to the immaturity of their immune system, premature infants are more vulnerable to infections; therefore, vaccination schedules must be carefully adapted based on gestational age, birth weight, and clinical stability rather than chronological age alone.

Modern clinical guidelines from the World Health Organization (WHO) and Centers for Disease Control and Prevention (CDC) emphasize that most routine vaccines should be administered to premature infants according to the same chronological schedule as full-term infants, provided the newborn is clinically stable. Special attention is required for extremely low birth weight infants, particularly regarding hepatitis B vaccination, where maternal HBsAg status significantly influences timing and dosing strategy.

**Keywords:** Premature newborns, immunization, neonatal vaccination schedule, immune system immaturity, hepatitis B vaccine, WHO guidelines, CDC recommendations, neonatal care, vaccine safety.

## Introduction

Immunization of premature newborns is a highly specialized area of neonatal preventive medicine focused on protecting infants born before 37 weeks of gestation from vaccine-preventable infectious diseases. Premature infants represent a high-risk population due to physiological immaturity of both innate and adaptive immune systems, reduced transplacental antibody transfer, and increased vulnerability to severe respiratory and systemic infections. According to the World Health Organization (WHO, 2023) and Centers for Disease Control and Prevention (CDC, 2024), vaccination of preterm infants should generally follow the same chronological age schedule as term infants, provided the infant is clinically stable, regardless of birth weight or gestational age.

The immunological rationale for early vaccination in premature newborns is based on the fact that vaccine-induced immune responses, although sometimes slightly lower in antibody titers, are still sufficient to provide protective immunity. Studies referenced in CDC Immunization Guidelines (2024) indicate that preterm infants develop adequate seroconversion rates for vaccines such as DTaP, IPV, Hib, and pneumococcal conjugate vaccine when administered according to standard schedules. However, the immune response may be less robust in extremely low birth weight infants (<1000 g), requiring careful post-vaccination monitoring.



**MAIN PART**

One of the most critical considerations in premature newborn immunization is hepatitis B vaccination. WHO (2023) recommends that infants born to HBsAg-positive mothers must receive hepatitis B vaccine and hepatitis B immunoglobulin (HBIG) within 12 hours of birth, regardless of gestational age or weight. For infants with birth weight <2000 g born to HBsAg-negative mothers, the first dose of hepatitis B vaccine may be delayed until 1 month of age or hospital discharge, depending on national protocols.

Clinical stability is a key requirement before administering vaccines to preterm infants. Stability parameters include adequate respiratory function without high oxygen dependency, stable cardiovascular status, and absence of acute infection or severe neurological compromise. In neonatal intensive care units (NICUs), continuous monitoring of oxygen saturation, heart rate, and respiratory rate is recommended for at least 24–48 hours after vaccination, particularly in infants with very low birth weight, as transient apnea and bradycardia episodes have been documented in clinical studies. From a pharmacological and immunological perspective, vaccine dosing in premature newborns does not require adjustment based on weight or gestational age. The standard principle supported by WHO (2023) and CDC (2024) is “same dose, same schedule,” with the exception of hepatitis B vaccine in specific risk groups. Vaccine antigens such as diphtheria toxoid, tetanus toxoid, acellular pertussis components, inactivated polio virus, and Haemophilus influenzae type b conjugate are all considered safe and immunogenic in preterm populations.

Safety monitoring is an essential component of immunization protocols in neonatal care. Common adverse effects include low-grade fever, injection site erythema, and mild irritability. Rare but clinically significant reactions include apnea, bradycardia, and oxygen desaturation episodes, particularly in infants born before 28 weeks of gestation. Therefore, many neonatal guidelines recommend inpatient observation after initial immunization in very premature infants.

Immunization of premature newborns is a critical component of neonatal preventive medicine designed to reduce morbidity and mortality from vaccine-preventable infectious diseases in a highly vulnerable population. Premature infants, defined as those born before 37 completed weeks of gestation, exhibit physiological immaturity of the immune system, including reduced neutrophil function, decreased complement activity, and limited transplacental IgG transfer, which occurs predominantly during the last trimester of pregnancy. This immunological deficiency increases susceptibility to invasive bacterial and viral infections, making timely vaccination essential.

From a clinical and epidemiological perspective, immunization protocols for premature newborns are primarily based on chronological age rather than corrected gestational age. According to WHO (2023) and CDC (2024) immunization frameworks, vaccines such as DTaP, IPV, Hib, and pneumococcal conjugate vaccine (PCV13/PCV15) are administered at 2, 4, and 6 months of chronological age, even in infants born at very low gestational ages, provided they are clinically stable. Clinical stability is defined as the absence of acute respiratory failure, hemodynamic instability, or active sepsis, and typically includes oxygen saturation  $\geq 90\%$  on minimal respiratory support.

Pharmacodynamic and immunogenic response studies demonstrate that preterm infants achieve protective antibody titers comparable to term infants, although mean geometric antibody concentrations may be slightly lower in extremely preterm neonates (<28 weeks gestation). Despite this, seroprotection rates remain clinically sufficient, supporting the “same dose, same schedule”



principle recommended by WHO (2023). Vaccine dosage is not adjusted for body weight or gestational age, with standard antigen quantities used universally across neonatal populations.

Hepatitis B immunization follows a modified algorithm based on maternal serostatus and birth weight. In infants born to HBsAg-positive mothers, hepatitis B vaccine combined with hepatitis B immunoglobulin (HBIG) must be administered within 12 hours of birth at separate anatomical sites. For infants weighing <2000 grams born to HBsAg-negative mothers, the initial vaccine dose may be deferred until 1 month of chronological age or hospital discharge, due to reduced seroconversion rates when administered immediately after birth.

Neonatal intensive care unit (NICU) monitoring protocols require continuous cardiorespiratory surveillance using pulse oximetry (SpO<sub>2</sub> monitoring), electrocardiography (ECG), and apnea detection systems for at least 24-48 hours post-vaccination in extremely low birth weight infants (<1000 grams). Documented adverse physiological responses include transient apnea episodes, bradycardia (<100 beats per minute), and oxygen desaturation (<85% SpO<sub>2</sub>), occurring in approximately 5-15% of very preterm infants following primary immunization.

The immunization schedule is typically structured as follows (chronological model):

1. Birth: Hepatitis B (selective indication based on maternal HBsAg status)
2. 2 months: DTaP, IPV, Hib, PCV
3. 4 months: Second doses of DTaP, IPV, Hib, PCV
4. 6 months: Third doses of DTaP, IPV, Hib (and influenza vaccine depending on season)

Cold chain management is a critical technical requirement, maintaining vaccine storage temperatures between +2°C and +8°C, with continuous temperature monitoring using digital data loggers to ensure antigen stability and potency.

From a risk-benefit analysis perspective, epidemiological data indicate that the risk of severe vaccine-preventable disease in unvaccinated preterm infants is significantly higher than the risk of serious adverse vaccine reactions. For example, pertussis-related hospitalization rates in unvaccinated preterm infants are reported to be 3-5 times higher than in term infants during the first year of life.

In conclusion, immunization of premature newborns is a strictly evidence-based clinical intervention guided by standardized international protocols. The “chronological age-based vaccination strategy,” combined with NICU-level monitoring and individualized risk assessment, ensures optimal immunogenicity, safety, and long-term protection against infectious diseases in this high-risk neonatal population.

## CONCLUSION

Immunization of premature newborns is a scientifically validated and essential intervention in neonatal healthcare aimed at preventing severe infectious diseases in a highly vulnerable population. Due to the immaturity of the immune system, preterm infants are at significantly increased risk of morbidity and mortality from vaccine-preventable infections; therefore, timely vaccination plays a critical role in improving survival outcomes.

Current international guidelines, including WHO (2023), CDC (2024), and AAP recommendations, consistently support the principle of “chronological age-based vaccination,” meaning that most vaccines should be administered according to the standard immunization schedule regardless of



gestational age or birth weight, provided the infant is clinically stable. This approach ensures adequate immunological protection without unnecessary delays.

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