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Editorial

Personalization of Neonatal Vaccination Timings Based on Established Evidence

Vaccination in the neonatal period is among the most effective public health interventions, contributing to reductions in childhood morbidity and mortality worldwide. WHO has endorsed universal birth-dose vaccines—hepatitis B (HBV), Bacillus Calmette-Guérin (BCG), and oral polio vaccine (OPV)—particularly in high-prevalence settings.[1] Large observational studies and pharmacovigilance systems have consistently demonstrated favorable safety profiles of these vaccines, with most reported adverse events being mild and transient.[2]

Concerns about long-term outcomes, including potential neuro-immunological ones, have been raised in theoretical contexts.[3] However, high-quality epidemiologic evidence is lacking. Systematic reviews have not identified increased risks of neurodevelopmental disorders such as autism spectrum disorder following routine immunization schedules, including the hepatitis B birth dose.[4] Differentiating between hypothesized mechanisms and outcomes supported by controlled studies is essential. Long-term surveillance should be regarded as a research priority, not an established risk.

In this context, Paymani and colleagues' review in the current issue of IJMS suggests a conceptual framework—the "As Low and Latest As Reasonably Achievable" (ALLARA) principle—for examining vaccination timing.[3] ALLARA, derived from radiation protection principles (where minimizing exposure is paramount), proposes a novel lens encouraging careful consideration of immunization timing relative to individual risk profiles. Notably, ALLARA has not yet been endorsed as a guideline in immunization and should be positioned as a proposed conceptual model that requires empirical validation through robust, prospective research.

The recent policy adjustment by the US Centers for Disease Control and Prevention (CDC) exemplifies how evidence and context inform immunization guidance. In December 2025, the CDC adopted a shared clinical decision-making approach for the hepatitis B birth dose among infants born to confirmed HBsAg-negative mothers, allowing clinicians and families to consider the timing of the first dose based on individualized risk factors.[5] This revision departs from over three decades of universal recommendation in the US and reflects epidemiological data indicating low HBV prevalence in pregnant women in some populations. Importantly, the updated recommendation preserves immediate birth-dose vaccination for infants of HBsAg-positive or unknown status mothers, in alignment with longstanding evidence that early prophylaxis prevents perinatal transmission.

Not all professional bodies have endorsed this change. For example, the American Academy of Pediatrics (AAP) continues to recommend the universal hepatitis B birth dose for all neonates, citing concerns about missed maternal infections and community transmission, and emphasizing the vaccine's strong safety profile.[6] Modeling studies, while sensitive to input assumptions, suggest that deferral of birth dosing could increase pediatric infections and associated long-term outcomes. Though such projections depend on local epidemiology and screening coverage.[7]

The implications of ALLARA can extend beyond HBV to other neonatal vaccines. BCG vaccination confers protection against severe forms of tuberculosis in high-burden settings, and some evidence suggests it may induce heterologous immune effects.[8] However, its efficacy varies by epidemiological context. In several low-TB incidence countries, selective BCG strategies have been adopted, along with robust surveillance systems.[9] Similarly, the global transition from OPV to inactivated polio vaccine (IPV) reflects risk-based policy evolution, as OPV's rare risk of vaccine-derived poliovirus becomes more prominent in underimmunized populations.[10]

These variations underscore the importance of tailoring immunization strategies to epidemiology, health system capacity, and population risk. WHO's global schedules continue to support universal birth doses when disease risk is substantial and maternal status is unknown.[1] In contrast, high-income, low-endemic settings with comprehensive maternal screening may consider individualized approaches based on local data.

Robust, long-term data are critical for evaluating both established and emerging vaccination strategies. Investments in longitudinal registries, post-licensure safety monitoring, and mechanistic immunology studies will strengthen understanding of how early immune exposures interact with developmental pathways. Precision tools—such as genomic markers of immune maturity or predictive modeling—hold promise for stratifying risk and optimizing timing, but such approaches must be validated across diverse populations before widespread implementation.

Finally, as personalized strategies develop, equity and access must remain central. Shared decision-making frameworks require adequate provider training, clear communication with families, and health system support to prevent disparities in coverage and outcomes.

To conclude, neonatal vaccination policies should be grounded in rigorous evidence, clear risk–benefit assessment, and continuous surveillance. The CDC's 2025 hepatitis B birth-dose recommendation update highlights how evidence and context can inform nuanced guidance. Suggested conceptual frameworks such as ALLARA may stimulate valuable scientific inquiry, but must be integrated with caution and empirical support. As vaccinology advances, interdisciplinary research and robust public health infrastructure will be key to optimizing immunization strategies that protect both individual and population health.

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