

Editorial Note on Challenges in Development of Neonatal Vaccines

Raajitha. B*

Department of Pharmacology, University of JNTUK, Guntur, India

Editorial Note

Vaccination stimulates a person's immune system to produce immunity to a specific disease, protecting the person from that disease. Vaccines are usually administered through needle injections, but can also be administered by mouth or sprayed into the nose. While vaccines have been tremendously successful in reducing the incidence of serious infectious diseases, newborns remain particularly vulnerable in the first few months of their life to life-threatening infections. A number of challenges exist to neonatal vaccination. However, recent advances in the understanding of neonatal immunology offer insights to overcome many of those challenges.

Potential Challenges in Development of Neonatal Vaccines

Practical

The complexity of vaccine development is compounded during the development of neonatal vaccines, as biomedical research primarily focuses on adults, and less is known about the function of the neonatal immune system.

Immunologic

The immune system of the new-born is functionally distinct and is considered as immunocompromised. Impaired production of TH1-polarizing cytokines by neonatal antigen-presenting cells (APCs), in part reflecting high cytosolic concentrations of inhibitory cyclic adenosine monophosphate, and increased activity of inhibitory neonatal T regulatory cells limit adaptive immune responses at birth.[5] Neonatal responses are thus often TH2-polarized. Moreover, maternal antibodies can inhibit responses to some antigens. Certain antigens, including BCG, engages the Toll-like receptor (TLR) system, can effectively activate TH1-polarizing neonatal adaptive immune responses in vitro and in vivo.

Safety

Neonatal immunization exists in the form of vaccines, such as BCG and hepatitis B vaccine (HBV), given to new-borns, which have an excellent safety profile. Nevertheless, safety concerns are paramount in the development of any new biologic agent, particularly ones that may be given to an entire population at birth. The potential benefits of neonatal vaccination are thus tempered by parental and medical concerns about safety. Biopharmaceutical development of neonatal vaccines will have to proceed with caution, but also within a viable development pathway given the urgent unmet needs and potential of immunization at birth.

Progress in development will require support for translational research in neonatal and infant immunology/vaccinology along with on-going optimization of practical regulatory guidelines for vaccine and vaccine adjuvant development such that safe and effective neonatal vaccines can be developed to meet the challenge of global infection.

*Corresponding author: Raajitha, Department of Pharmacology, University of JNTUK, Guntur, India. E- mail: raajitha.nrt@gmail.com

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