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Update on global prevention of pneumococcal infection; expanded conjugate vaccines and new pneumococcal protein vaccines, implications of Gavi graduation, and serotype replacement

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Pneumococcal disease remains a major cause of morbidity and mortality in young children, particularly in low- and middle-income countries (LMICs). Vaccines are a critical strategy for protecting children from pneumococcal disease and licensed pneumococcal conjugate vaccines (PCVs) are having a significant impact on reducing invasive pneumococcal disease and pneumonia throughout the world. Currently available PCVs do not, however, cover all pneumococcal serotypes and are complicated and relatively expensive to manufacture, driving prices up. New PCV development is focused on either higher valency or more inherent affordability for LMICs. One of the latter vaccines is Serum Institute of India Pvt. Ltd.'s PCV-10 (PNEUMOSIL®). A Phase 3 trial with SIIPL-PCV10 was recently completed in The Gambia and the data demonstrated lot-to-lot consistency, immunological non-inferiority compared to the licensed PCV-10 Synflorix®, and non-interference with co-administered Expanded Program on Immunization vaccines. Lower cost PCVs, like PNEUMOSIL®, manufactured by vaccine manufacturers from emerging economies have the potential to play an important role for freeing up Gavi, the Vaccine Alliance and country funds for other public health priorities; enabling PCV access for middle-income countries ineligible for Gavi pricing; and sustaining access for countries transitioning from Gavi eligibility. Higher valency (15+ valent) PCVs are in various stages of development, some of which incorporate novel conjugation technologies designed to simplify manufacturing processes or reduce the phenomenon of carrier suppression seen with high-valency vaccines.

Since PCVs do not protect against all 90+ pneumococcal serotypes (even with added strain coverage) efforts are ongoing to develop common protein-based pneumococcal vaccines with the potential to broadly protect across the full spectrum of pneumococcal serotypes and avoid serotype replacement. Preclinical studies have demonstrated that protein vaccine candidates can protect against both nasopharyngeal carriage (NPC) and invasive disease—protection mediated by distinct immunological mechanisms (antibody and cell-mediated immunity). Protein vaccines, either alone or used in combination with PCVs, have advanced into Phase 1 and 2 clinical trials and have been demonstrated to be safe and immunogenic. The potential for these vaccines to impact NPC and otitis media is being explored in proof-of-concept studies in children. Demonstrating impact on invasive disease and pneumonia will, however, likely be required for product licensure. Despite their potential, pneumococcal protein vaccines face considerable challenges before they can become licensed and widely distributed.