A new pneumococcal vaccine is here! Why this matters.

With a recent approval from the World Health Organization, this high-quality, more affordable vaccine is poised to help more countries access protection against the top cause of deadly childhood pneumonia.

Imagine it's 2008. A pediatric pneumococcal vaccine has been available for years and made incredible strides against pneumonia and other pneumococcal diseases (like meningitis, sepsis, and disabling middle-ear infections). In the United States and other high-income countries, that is.

Hundreds of thousands of kids still die from pneumococcal disease unnecessarily in low- and middle-income countries. Barriers such as vaccine price and availability are preventing them from accessing this lifesaving tool. Furthermore, the vaccine doesn't yet target some of the most threatening kinds (serotypes) of the pneumococcus bacterium for children in these parts of the world.

That same year, Serum Institute of India, Pvt., Ltd. and PATH kick off a collaboration with funding from the Bill & Melinda Gates Foundation to do the difficult job of developing a pneumococcal vaccine that not only provides the protection that children in these settings need but breaks down inherent price barriers to access.

Jump ahead to today and there's reason to celebrate. The Serum Institute vaccine that was merely an ambitious idea over a decade ago has just been WHO-prequalified and will be made available to low- and middle-income countries for a target of US$2 per dose, an unprecedentedly low price for any pneumococcal vaccine.

Each year, nearly 400,000 children under five years of age die globally from pneumococcal disease, mostly in Africa and Asia. WHO prequalification opens the door for this new vaccine, PNEUMOSIL®, to bolster the prevention toolkit and fulfill its purpose—to save more lives by enabling access that countries in these regions can afford and sustain long term.

Why is price so important?

Pneumococcal vaccines that can be given to children are conjugate vaccines, which are the most complex kinds of vaccine to manufacture and relatively expensive as a result. In Pan American Health Organization countries, for instance, they run around US$12.85 to 14.50 per dose depending on the vaccine. And these vaccines require at least three doses in kids. Working together through complex financing mechanisms, global health donors and vaccine manufacturers have helped pneumococcal conjugate vaccines become available for low-income countries at significantly reduced prices—enabling rollouts in these settings to begin in 2009. This supported price is around $3 per dose today, which countries co-pay with heavy contributions from Gavi, the Vaccine Alliance.

Although such support has enabled broader access and saved countless lives, pneumococcal vaccine programs continue to be difficult for many low-income countries to sustain due to cost and are at even greater risk once countries graduate from Gavi financial support. Other countries ineligible for financial support (especially middle-income nations) have never even introduced pneumococcal vaccines into their national immunization programs, one factor being because prices are prohibitive. Paying for pneumococcal vaccines also consumes a disproportionate amount of donor resources compared to other vaccines—nearly half of Gavi's funding for vaccine acquisition, for example.

Overall, PNEUMOSIL®'s target $2 per dose price is roughly 30% lower than the Gavi price and dramatically lower for non-Gavi low- and middle-income countries. Such savings will not only help more countries sustain and/or introduce pneumococcal immunizations, but donor and country funds could be freed up for other important public health priorities—contributing even more broadly to improving health and survival. Lower prices also complement other efforts to leverage common resources to fight multiple diseases at once such as pneumonia and diarrheal disease.

What does it take to bring the price down?

A child receives routine immunizations, including pneumococcal vaccine, at a clinic in The Gambia—a representative setting where a more affordable pneumococcal vaccine could be beneficial. Photo: PATH/Lauren Newhouse

Prior to partnering on PNEUMOSIL®, Serum Institute and PATH had already worked together with other partners on another high-quality, low-priced conjugate vaccine against meningitis A—MenAfriVac®. Developed upon request from health ministers in Africa's meningitis belt, the vaccine has essentially wiped out meningitis A disease where introduced. For this successful vaccine, Serum Institute optimized more efficient conjugate vaccine manufacturing processes that it, in turn, applied to bring PNEUMOSIL®'s price down as well. Overall, innovating on PNEUMOSIL®'s conjugation technology and working out the process to generate very high yields contributed greatly to producing higher volumes of vaccine more quickly—and helped lower the prices substantially.

Selecting the most appropriate serotypes to target with PNEUMOSIL® was also key to minimizing cost. The pneumococcus has over 90 serotypes that vary by region, but conjugate vaccines are only able to cover a limited number of them. Since each serotype added to a conjugate vaccine adds cost, those included in PNEUMOSIL® are among the 10 likeliest to sicken and kill children in Africa, Asia, and Latin America. This maximizes coverage where the vaccine is intended for distribution without the added cost of unnecessary serotypes. In this way, PNEUMOSIL®'s coverage is estimated to be comparable in these regions to other prequalified pneumococcal vaccines on the market.

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And then there were three

Two other pneumococcal vaccines for kids are currently WHO prequalified and are effective at preventing disease caused by the serotypes of pneumococcus they are designed to protect against. Achieving the landmark of WHO prequalification for a new PCV, however, is not easy. Since the initial licensure of the first PCV 19 years ago, only one other vaccine manufacturer has managed to achieve this goal. To become WHO prequalified, a vaccine must meet international standards for manufacturing quality and perform well in a series of rigorous preclinical and clinical evaluations designed to demonstrate safety and acceptable immune responses.

Accordingly, PNEUMOSIL® has undergone the required clinical development program in The Gambia and India, including a pivotal Phase 3 clinical study in The Gambia whose results support the vaccine's safety and ability to elicit comparable infant immune responses to a prequalified vaccine. In short, this means that the vaccine is expected to perform on par with other vaccines in its class, expanding the suite of options from which countries can choose.

What now?

As PNEUMOSIL®'s prequalification marks a huge milestone allowing the vaccine to be put to use, now's the time to set about additional work that will help it achieve its full public health potential and impact. In this vein, ongoing studies include a Serum Institute-sponsored evaluation in India for marketing authorization within the country, as well as a study conducted by PATH and partners in The Gambia to examine an additional WHO-recommended dosing schedule. Spreading the word about this new addition to the toolkit is also important so that countries can make informed decisions for pneumococcal prevention and other public health priorities. Additional studies will also be needed to evaluate the vaccine's performance in real life prevention of pneumococcal disease, once introduced into communities.

Now, after more than a decade of anticipation, we finally have a new tool that could help overcome some of the most persistent roadblocks plaguing pneumococcal disease prevention. Let's make sure to put it to good use.