

One shot to stop Group B *Streptococcus*



Developing a first-of-its-kind vaccine to save newborn lives

Group B *Streptococcus* (GBS), also known as *Streptococcus agalactiae*, is the leading cause of sepsis and meningitis in young infants worldwide—often affecting babies just a few hours old.

GBS isn't well known—it's often not discussed outside the context of pregnancy and childbirth—but it can have deadly consequences. Studies estimate GBS could be responsible for as many as 3.5 million preterm births and nearly 150,000 stillbirths and infant deaths annually.¹

Babies that survive the bacterial infection are often left with lifelong disabilities such as deafness, blindness, and developmental delays. GBS may also play a role in miscarriage.

Current prevention methods

GBS bacteria live in the gastrointestinal tract and the vagina. Nearly 20 percent of women worldwide carry the GBS bacterium, which can be passed from mother to baby during birth.¹

No licensed vaccine against GBS currently exists. Prevention methods rely on screening and prophylactic antibiotics.

In some high-resource countries women are screened for GBS colonization using vaginal and rectal swabs at 35 to 37 weeks of pregnancy. Women who test positive for GBS colonization are given prophylactic antibiotics intravenously during labor to help prevent infection of their baby.

Antibiotic prophylaxis significantly reduces the likelihood of passing the infection from mother to baby—from 1 in 200 to 1 in 4,000.¹ But, preventative antibiotics are only effective against one category of GBS infection in infants: early-onset disease (EOD), which occurs during the first seven days of life and is nearly always passed from mother to baby during birth. All babies—even those born to mothers who don't carry the bacterium—are vulnerable to late-onset disease (LOD), which occurs from one week to three months following birth without any clear source of transmission.

Conservative estimates indicate every year more than 200,000 babies contract EOD and more than 110,000 contract LOD.¹

The global disease burden

Combatting GBS disease is a difficult task; current screening



A Group B *Streptococcus* vaccine has the potential to protect infants around the world from a deadly infection common in the first few days of life. Photo: PATH/Gabe Biencycki.

and prevention methods are expensive and practical only in high-income countries; and, even within these high-income countries, recommendations regarding screening and antibiotic prophylaxis vary.

Complicating matters is that global disease burden is not well-understood. Many countries likely underestimate GBS disease incidence; other countries don't have incidence numbers at all.

What is known is that GBS disease burden is significantly higher in low-resource countries than in high-resource ones because preventative screening and antibiotic prophylaxis are impractical, expensive, and out of reach for most women.

Across Africa, for instance, studies estimate 8 million infants are exposed to GBS annually, leading to 169,000 cases of infant disease; 42,000 stillbirths; 54,000 infant deaths; and 6,400 infants who suffer moderate-to-severe long term disabilities.¹

To truly prevent GBS we need a safe, effective, and affordable vaccine that can be given during pregnancy, thereby reducing the risk of newborn infection and providing babies around the world with critical protection through the first three months of life.

Protecting infants by protecting mothers

Direct vaccination, which works for older infants and children, is

often not an effective option for newborns. Babies are born with immature immune systems not yet able to adequately respond to many vaccines, which consequently must be given later in childhood. Moreover, because GBS infections often occur in the first few days of life, a vaccine immune response wouldn't have sufficient time to develop.

Maternal immunization is a promising way to bridge this infant immunization gap.

After getting vaccinated, a pregnant mother's antibodies are passed to her baby and can protect her infant before birth during the first few days and months of her infant's life. Maternal immunization has a safe and effective track record against other diseases that afflict newborns, including tetanus, influenza, and pertussis (whooping cough).

Maternal immunization is an ideal strategy for preventing GBS disease because it would provide babies with protection before they are exposed to the GBS bacterium.

A better solution

PATH is working with partners globally to develop a vaccine against GBS.

A GBS vaccine has potential all over the world, but would have the greatest impact in low-resource countries that have limited

access to interventions. As such, we are directing our support to the places that need help the most: the vaccine is being developed in South Africa, which has one of the highest rates of infant GBS disease in the world.

PATH is supporting The Biovac Institute in Cape Town as it works to develop a multivalent, conjugate vaccine against GBS—a vaccine that uses the most advanced technology and targets the most common strains.

This project will help Biovac strengthen its vaccine development capabilities and establish its position as an essential producer. It would position Biovac to be only one of a handful of companies in the world, and the only developing-country vaccine manufacturer, to develop a vaccine against GBS.

Inventprise, a Seattle-area biotechnology startup with conjugate vaccine development expertise, is providing technical support.

A GBS vaccine would initially target South Africa and the surrounding countries, but eventually could extend to populations around the globe.

The vaccine candidate is currently in preclinical development, with the first clinical trial planned to begin in 2020.

¹ Seale AC, Bianchi-Jassir F, Russel NJ, et al. Estimates of the Burden of Group B Streptococcal Disease Worldwide for Pregnant Women, Stillbirths, and Children. *Clinical Infectious Diseases*. 2017;65(Suppl 2):S200-219.



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