

Advancing a vaccine against Group B *Streptococcus*



A promising tool to save newborn lives

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

Anyone can contract GBS. The bacteria live in the gastrointestinal tract, rectum, and vagina. It's common and generally benign in adults; nearly 20 percent of women worldwide carry the GBS bacterium.¹ But it can be passed from mother to baby during birth—and it can be deadly for infants. Studies estimate that, annually, GBS could be responsible for more than half a million preterm births; 46,000 stillbirths; and 91,000 infant deaths.² GBS can also cause miscarriage. Survivors are at risk, too: babies that survive the bacterial infection are often left with lifelong disabilities such as deafness, blindness, and developmental delays.

No licensed vaccine against GBS currently exists, though the tide could soon turn as several are in development.

Current prevention methods

Current GBS prevention methods rely on screening and prophylactic antibiotics. In some high-resource countries, women are screened for GBS colonization at 35 to 37 weeks of pregnancy. Women who test positive are given prophylactic antibiotics intravenously during labor to help prevent the infection from passing to their baby. This can significantly reduce the likelihood of infant infection—from 1 in 200 to 1 in 4,000.³

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 230,000 babies contract EOD and more than 160,000



PATH is supporting a Phase ½ study of Inventprise's Group B *Streptococcus* 6-valent conjugate vaccine candidate. Photo: PATH.

contract LOD.¹

Moreover, antibiotic use is not without risk; it can contribute to antibiotic-resistance and possibly alter a baby's microbiome.

The global GBS disease burden

Combatting GBS disease is a difficult task. Current screening and prevention methods are expensive and feasible only in high-income countries; and, even within these high-income countries, recommendations vary regarding screening and prophylaxis.

In low-resource countries, preventative screenings and antibiotic prophylaxis are impractical, expensive, and out of reach for most women—which leads to these countries experiencing a significantly higher disease burden.

In high-income countries, the GBS mortality rate is estimated to be between 6 and 14 percent, but in low- and middle-income countries, it's estimated to be between 10 and 60 percent—a stark difference that highlights the inequity in access to health care resources. Sub-Saharan Africa, in particular, is hard hit; studies

estimate that nearly half of all GBS-related infant deaths globally occur there.

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 vaccination, a pregnant mother's antibodies are passed to her baby and can protect her infant before birth and during the first 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 ever exposed to the GBS bacterium.

Our solution

Since 2016, PATH and Seattle-area biotechnology company Inventprise Inc. have been working to develop a vaccine against GBS that can be delivered during pregnancy, thus allowing protective antibodies to pass from the pregnant woman to the baby in utero.

We're pursuing a multivalent conjugate vaccine—a vaccine that targets the most common strains of the disease and uses the most advanced technology. The vaccine candidate covers six different GBS strains,

including the five most common strains globally and a sixth that is currently seen in south Asia.

This is ideal because research shows that a vaccine targeting five of the most common GBS strains would prevent 99 percent of GBS-related stillbirths and between 98 and 99 percent of GBS cases globally.⁴

In November 2024, the vaccine candidate entered Phase 1/2 clinical study at New York University's Langone Health Vaccine Center; and in May 2025, a second clinical site was initiated at the University of the Witwatersrand Vaccines and Infectious Diseases Analytics Research Unit in Johannesburg, South Africa. Between New York and South Africa, the vaccine candidate will be delivered to 600 healthy, non-pregnant women between 18 and 49 years of age.

The study will examine the safety, tolerability, and performance of the vaccine candidate, and will pave the way for larger studies that examine the vaccine candidate's performance in the populations it was designed for.

Study results are expected in late 2026.

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