UK Health Security Agency

Case Study
Discovery & Surveillance
(Vaccine Assay & Immune Response)

Group B Streptococcus

Group B Streptococcus (GBS) is the leading cause of vaccine-preventable infections in neonates in the developed world, and a significant cause of neonatal infections and stillbirths worldwide.

Group B Strep

Target

GBS is a leading driver of antibiotic use in a neonatal setting, and antimicrobial resistance is increasing. To reduce early-onset disease (usually within the first 48h of life) many countries have introduced screening for GBS in pregnancy, where culture positive mothers are given intravenous antibiotics in childbirth to protect both the mother and the infant. As a result, this has dramatically increased the use of antibiotics in childbirth. In some countries >50% of childbirths now involve intravenous antibiotic use.

Aims

A maternal vaccine for GBS which protects infants from both early and late onset disease (for which intrapartum antibiotics have no effect) will have not only a positive impact on infant mortality and morbidity but will also lead to a dramatic reduction in the use of antibiotics in neonatal units worldwide.

Issues

Reduction of antibiotic use in neonates will allow the development of appropriate commensal gut bacteria, enabling them to digest milk and reduce the risk of antimicrobial resistance.

Options

The Pathogen Immunology Group at UKHSA, Porton Down had previously been part of an international consortium to develop standardised correlates of protection to allow the evaluation of new GBS vaccines and enable licensure of the leading candidates (GASTON consortium). UKHSA Porton successfully developed a “Gold Standard” opsonophagocytosis killing assay (OPKA) and led a global interlaboratory study of the OPKA in public health, academic and industry labs. The assay was shown to be highly sensitive and reproducible in different laboratories, and standard GBS test strains have been selected by UKHSA and made available worldwide.

Outcome

Licensure of a GBS vaccine will not only prevent the deaths of 10s of 1000s of neonates worldwide, it will also reduce the need for antibiotic treatment in disease cases and have a direct impact on reducing the need for intrapartum antibiotics during childbirth.

Future work

As part of this project, the team has also developed an OPKA for GBS serotype VII, which will be used in a follow-up PATH-funded Phase I/II clinical study of a novel 6-valent GBS vaccine currently being developed.

VDEC USP

In 2022-2023, follow-on funding was awarded by BMGF to

develop a higher-throughput version of the OPKA

suitable for Phase II/III clinical trials and to provide international reference serum samples with defined units of opsonophagocytic activity.

The high throughput OPKA is required as the current assay method is very labour-intensive which

limits the number of sera that can be analysed in large vaccine studies.

Work with VDEC

We work with industry, academia and government. Contact UKHSA today to see how we can help you.

Get in touch: **vdec@ukhsa.gov.uk**