FULL VALUE OF VACCINE ASSESSMENT

GROUP B STREPTOCOCCUS VACCINE

EXECUTIVE SUMMARY

LONDON SCHOOL of HYGIENE &TROPICAL MEDICINE

World Health Organization

Group B streptococcus vaccine: full value of vaccine assessment. Executive summary

ISBN 978-92-4-003809-7 (electronic version)

ISBN 978-92-4-003810-3 (print version)

Suggested citation. Group B streptococcus vaccine: full value of vaccine assessment. Executive summary. Geneva: World Health Organization; 2021. Licence: CC BY-NC-SA 3.0 IGO.

Cataloguing-in-Publication (CIP) data. CIP data are available at http://apps.who.int/iris.

Cover photo credit: Louis Leeson/LSHTM2017

SUMMARY

Group B streptococcus (GBS) is an important cause of disease burden in every region worldwide, contributing to neonatal/ infant infection, deaths, disability, stillbirths and maternal infection. The World Health Organization (WHO) identified the development of GBS vaccines suitable for maternal immunization in pregnancy and use in low- and middle-income countries (LMICs) as a priority in 2015. The purpose of this report, WHO Full value of vaccines assessment of Group B streptococcus vaccines is to describe the global public health rationale for developing vaccines against disease caused by GBS for maternal immunization, to inform decision making across the continuum of vaccine development and uptake with a line of sight to sustainable public health impact.

Key audiences include:

1. vaccine research and development community;
2. funders of research and vaccine implementation;
3. global policy-makers;
4. national policy-making bodies and health planners.

This full value of vaccines assessment (FVVA) provides evidence that:

- The global burden of GBS is higher than previously recognized, and includes GBS neonatal/ early infant meningitis, sepsis, death, and neurodevelopmental impairment, with additional GBS-attributable stillbirth, maternal sepsis and GBS-associated preterm births. The burden is highest in sub-Saharan Africa and South Asia.
- Vaccination could result in substantial declines in global morbidity and mortality due to GBS. A maternal vaccine is likely to be a cost–effective intervention, with a positive global net monetary benefit under most assumptions if the vaccine is affordably priced.
- GBS vaccine development is financially sustainable and likely to be profitable from the manufacturer perspective globally, subject to adoption in high-income countries.
- A maternal vaccination programme would be feasible to implement, requiring increased awareness of GBS as a public health challenge as well as strengthening of health systems for delivery, monitoring and evaluation.
- There are information gaps that if filled could further reduce uncertainty, including prospective data on GBS maternal colonization and preterm births, as well as stillbirths and maternal infections. Health economic data are only available in a few low- and middle-income settings and more data from countries in a range of different settings would improve economic evaluations.
- There is heterogeneity in disease burden, vaccine cost–effectiveness and programmatic preparedness by region and country, emphasizing the need for local assessment and decision-making with tiered and fair vaccine pricing.

Priority areas for further support for GBS vaccine development and implementation preparedness are:

- to define correlates of protection to facilitate vaccine licensure;
- to develop tools and evaluation frameworks, including surveillance standards;
- to support country-level assessments and decision-making;
- to establish ongoing monitoring through routine systems.

SUGGESTED NEXT STEPS

Further discussion at global level will be helpful to assess additional evidence and information that is being generated and to translate this information into action and policies that will enable the research and development community to develop a GBS vaccine optimized for use in low resource settings as well as national decision-makers to prepare their countries to introduce GBS vaccine in pregnant women.

The pathway to licensure for a GBS vaccine has not yet been agreed by regulators. Evidence to support licensure based on immunogenicity studies and correlates of protection is a priority and much work in this area is ongoing. The financial sustainability analysis suggests that this will increase the attractiveness of GBS vaccine development to manufacturers.

A reliance on modelled estimates of disease burden is inevitable when many countries do not have high-quality surveillance systems for infant infections and deaths. Uncertainty in disease burden estimates are propagated through the analyses of potential vaccine impact. Additional data on GBS-attributable stillbirth, especially from Asia, would be welcome, and few studies have been conducted on maternal sepsis due to GBS outside of high-income settings. Strengthening surveillance, including microbiological confirmation, is important for good local decision-making before vaccine introduction and monitoring vaccine impact. Surveillance is one of the five pillars of the Defeating meningitis by 2030 road map *(33)*, which will provide technical support for countries.

Further studies, in particular well-designed prospective studies, with comprehensive exposure measures are necessary, especially to further elucidate the association between GBS infection and maternal sepsis, stillbirths and preterm births. If a GBS vaccine were to reduce preterm births, the net monetary benefit would be positive in most settings. There was insufficient evidence to develop an extended cost-effectiveness analysis *(96)* to examine the equity implications of a GBS vaccine, but this is an important area for further research.

The development of tools and frameworks to support LMICs in addressing issues of optimal service delivery, likely GBS vaccine acceptance, and monitoring and evaluation should be a priority. Synergies with other maternal immunization programmes should be investigated, including new vaccines in development.

Principal findings, the quantitative data behind these, interpretation and next steps for different stakeholders

Principal finding	Quantitative assessment	Interpretation	Next steps
New estimates of global neonatal/ infant infections in 2020 illustrates high burden of GBS disease	Annual burden: iGBS (392,000, UR 184,000–849,000), deaths (91,000, UR 44,000–187,000), stillbirth (46,000, UR 20,000–111,000), neurodevelopmental impairment (40,000 new cases, UR 14,000–112,000) and GBS associated preterm births (518,000, UR 36,000–1,142,000)	Disease burden provides strong rationale for vaccine development for all stakeholders	Technical and financial support is required to strengthen country-level surveillance and burden assessments, including health economic data
Vaccination could result in substantial declines in global morbidity and mortality due to GBS	3,841,000 QALYs gained per year globally (base case)	Maternal GBS vaccination will substantially reduce burden of disease	Global Policy makers should recommend Funders and Countries to prioritise GBS vaccines
A maternal vaccine is likely to be a cost-effective intervention, with a positive global net monetary benefit under most assumptions	Global net monetary benefit of US$ 1–17 billion	Vaccination is likely to be cost-effective at competitive prices	Industry should provide GBS vaccines at fair prices. Funders of vaccine implementation and National policy makers should invest in GBS vaccines if prices are competitive
GBS vaccine development is financially sustainable and likely profitable, subject to adoption in high-income countries	Net present value: US$ 742 million (base case)	High NPV will motivate Vaccine Researchers & Developers (R&D) to take GBS vaccine candidates through to registration	Vaccine R&D and funders should discuss how to accelerate vaccine development for use in low resource settings
Awareness of GBS is low in many LMICs and systems strengthening needed for vaccine implementation, monitoring & evaluation	N/A, findings supported by literature reviews and surveys	Countries and national policy makers may not recognise the potential value of GBS vaccines	National level stakeholders and Funders should jointly address core success factors of future vaccine introduction and secure funding for sustainable use
There is clear global value in a	Regional variation in disease burden	Such heterogeneity	National level stakeholders