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PERSPECTIVES

Maternal Group B *Streptococcus* Vaccination: A Three-Country European Consortium to Improve Surveillance and Data Readiness

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Background: Group B *Streptococcus* (GBS) is a common gut coloniser, yet it can cause serious disease in pregnant women, newborns, and in adults with predisposing conditions. Estimates suggest that approximately 20 million pregnant women are colonised with GBS, and 394,000 cases of invasive disease occur in infants every year, but there are many data gaps. Several countries lack robust data, leading to likely underestimation of the true disease burden, notably for GBS-associated stillbirths and preterm births.
Objective: Recent progress in the development of maternal GBS vaccines adds urgency to the need for comprehensive surveillance data. The aim of this study is to describe advances in routine health information systems and record linkage offer new opportunities for robust monitoring and research on GBS outcomes, both before and after vaccine roll-out.
Approach: This review article identifies crucial research gaps, proposes priority outcomes that should be monitored, and highlights opportunities to use routine data from three European countries (Denmark, the Netherlands, the United Kingdom) to harmonise data and strengthen the evidence base to inform national GBS vaccine policy decisions.
Conclusion: Strengthening and harmonising routine data collection across Europe and globally will be essential to maximize and measure the benefits of a maternal GBS vaccination.
Keywords: Group B *Streptococcus*, maternal vaccines, health registries

Background

Group B *Streptococcus* (GBS) or *Streptococcus agalactiae*, a β-haemolytic Gram-positive coccus, may be harmless in most healthy individuals but can cause invasive infections in pregnant women, newborns, or in adults with predisposing conditions. Global burden estimates for 2020 predicted a high number of women with GBS colonisation (19.7 million) resulting in invasive GBS disease in mothers (40,500) and infants (394,000 cases).[1] Deaths due to invasive GBS disease in early infancy were predicted to be 91,900 annually, with many survivors predicted to develop moderate or severe neurodevelopmental impairment (37,100 cases per year).[1] GBS was also found to be an important cause of stillbirths (46,200) and estimated to be associated with 3.5% of all preterm births worldwide (more than 0.5 million cases).[1] The burden was highest in low-income and middle-income countries.[1,2]

Accurate estimates of disease burden are essential for guiding and evaluating the impact of GBS prevention strategies, particularly for new vaccines. However, data on GBS remain limited in many countries, potentially leading to an

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underestimation of the disease burden. Globally, there are 1.9 million stillbirths (after 28 weeks gestation) and 13.4 million preterm births per year – whilst GBS contributes to these outcomes, there is considerable uncertainty on the proportion attributable to GBS due to data gaps, even in high-income contexts. High-quality data are therefore urgently needed. Moreover, data on long-term neurodevelopmental impairments in neonatal survivors of invasive GBS disease are critical to understand the full disease burden and societal impact but lacking in many countries.[3,4]

GBS prevention has relied on intrapartum antibiotic prophylaxis (IAP), either through universal prenatal culture screening or risk-based screening. IAP has notably decreased early-onset GBS disease, but only in settings with high coverage and its implementation remains challenging in many contexts due to laboratory processing requirements. Furthermore, IAP does not prevent late-onset GBS disease, has no effect on stillbirths or preterm births, and increases antibiotic exposure, with potential negative consequences for antimicrobial resistance (AMR) and neonatal microbiome risks.[5]

Current Status of GBS Vaccine Development

Effective and affordable maternal vaccines have the potential to address the challenges of current GBS preventive strategies. By providing direct protection to both mothers and their infants, vaccines could reduce the incidence of invasive GBS disease, stillbirths, and preterm births, while also reducing antibiotic use. According to economic modelling, GBS maternal vaccination is likely to be cost-effective, depending on its efficacy and pricing.[2] An 80% effective vaccine was estimated to potentially avert 214,000 infant cases and 54,000 stillbirths and neonatal deaths annually, depending on coverage, and to be cost-effective alongside current prevention efforts, depending on vaccine pricing.[2] In 2015, the World Health Organization (WHO) identified the development of a maternal vaccine against GBS as a priority, and licensure of an affordable vaccine by 2030 is an important milestone in the WHO Global Roadmap for Defeating Meningitis.[6]

Two GBS vaccines are in late-stage clinical development: (i) GBS6 (manufactured by Pfizer), a hexavalent polysaccharide CRM197 conjugate vaccine against serotypes Ia, Ib, II, III, IV and V, covering a high proportion of disease-causing isolates worldwide[7,8] and (ii) GBS-NN/NN2 (manufactured by MinervaX), a protein subunit vaccine consisting of the N-terminal domains of aC, Rib Alp1 and Alp2/3, also covering a high proportion of clinical GBS isolates.[9,10] Several other vaccines are in early clinical or preclinical stages (Table 1).[11]

Given the large number of participants required for traditional Phase III clinical endpoint trials to achieve vaccine licensure, alternative pathways are being applied based on an immunological endpoint capable of predicting clinical benefit (a serological threshold of risk reduction).[12] Observational studies measuring clinical outcomes of effectiveness

Table 1 Maternal Group B *Streptococcus* Vaccines

Vaccine Type	Pre-Clinical	Phase I	Phase II	Phase III
Conjugate vaccine	Affinivax, Inc. (GSK) CPS+GBS-SP *[M]*	Inventprise. IVT GBS-06 Hexavalent *[M]*	Novartis/GSK CRM Trivalent **Inactive [M/HIV]*	Pfizer CRM Hexavalent **Started 2025 [M]*
	BioVac CPS+GBS-SP *[M]*		Pfizer CRM Hexavalent ± DTaP (n-preg) **April 2023 [M]*	
			Pfizer CRM Hexavalent **March 2024 [M]*	
			Pfizer CRM Hexavalent **Sept 2024 [M/HIV]*	

(*Continued*)

Table 1 (Continued).

Vaccine Type	Pre-Clinical	Phase I	Phase II	Phase III
Protein subunit vaccine	Beijing Pharmatech GBSV6 *[M]*	Minervax GBS-NN/NN2 *May 2024 *[O]*	Minervax GBS-NN/NN2 **Sept 2023 [M]*	Minervax GBS-NN/NN2 **Start 2026 [M]*
			Minervax GBS-NN/NN2 **July 2023 [M/HIV]*	

Note: *Results.
Abbreviations: CPS, Capsular polysaccharides; CRM, cross-reacting material 197; DTaP, diphtheria and tetanus toxoids and acellular pertussis; GBS, group B *Streptococcus*; GBS-SP, group B *Streptococcus* surface proteins; HIV, human immunodeficiency virus; IVT, in vitro transcribed; M, maternal; O, older adult.

and safety post-licensure will subsequently be necessary to inform policy and support wider uptake. National data registry systems in some European countries are well positioned to provide such data.

GBS Vax-Ready European Consortium

The *GBS Vax-Ready European Consortium* was established during an expert workshop held in Denmark on 1–-3 April 2025 and it brings together leading research and public health institutions from three European countries: Denmark, the Netherlands, and the United Kingdom. These countries have comprehensive national data registry systems and have previously worked together to analyse GBS data in a comparable way.[3,13]

The consortium aims to leverage existing routinely collected health data to address key evidence gaps to inform GBS vaccine licensure and track post-vaccine roll-out. Its three focus areas are: (1) use current routine data to address priority outcome data gaps to inform GBS vaccine implementation in multiple countries, (2) increase data comparability and linkage to enable surveillance readiness post-vaccine roll-out, and (3) inform strategies to optimise and equitably reduce GBS burden and mitigate AMR worldwide.

Pre- and Post-Vaccine Introduction Studies

Knowledge Gaps and Opportunities for National Analyses

The consortium aims to combine high-quality, routinely collected health registry data with reference laboratory data to address priority evidence gaps for GBS. National data from the three countries, and potentially other countries, can help reduce uncertainties in GBS burden measurement. The United Kingdom's National Health Service provides universal, tax-funded healthcare through a primarily publicly owned and operated system.[14] Denmark maintains a highly centralised, tax-funded healthcare system with strong primary care and universal coverage.[15] The Netherlands operates a regulated insurance-based healthcare system in which all residents are required to obtain private health insurance.[16]

In the United Kingdom, as a result of a national surveillance study undertaken in 2000–2001, the first national prevention guideline was issued in 2003 by the Royal College of Obstetricians and Gynaecologists. This recommended a risk factor approach to the use of IAP. A universal screening strategy was rejected by the national screening committee in 2017 due to lack of randomised controlled trial evidence, a gap now addressed by the recently completed GBS3 trial. In Denmark, national guidelines for risk-based IAP were introduced in 1997. Early-onset neonatal GBS incidence decreased from 0.6 per 1000 livebirths in 1995 to 0.1–0.3 per 1000 live births after 1997, coinciding with implementation of the national guideline. The Netherlands implemented a risk factor-based early-onset sepsis prevention strategy in 1998. Surveillance data are derived from the Netherlands Reference Laboratory of Bacterial Meningitis, which receives GBS isolates with an estimated 85–90% coverage of blood and cerebrospinal fluid isolates Despite risk factor-based IAP strategy, the incidence of invasive GBS disease in the Netherlands increased from 0.19 per 1000 livebirths in 1987 to 0.57 in 2023.

These three countries provide a foundation for addressing existing knowledge gaps, given their similar healthcare systems and nationally representative, health, laboratory, and administrative data, enabling record linkage on individual-

level, comprehensive follow-up, selection of large study cohorts, and effective confounder adjustment. Although these three countries share many similarities in healthcare access and data completeness, their differences also provide opportunities to study GBS across these health systems, and to explore ways to overcome data comparability challenges, yielding insights transferable to other countries aiming to use routine data.

We selected outcomes to be evaluated for large-scale pre- and post-vaccine introduction studies based on the outcomes measured in burden of disease estimates for GBS in pregnancy and used in several cycles of estimates for 195 United Nations member states.[1,17,18] These outcome measures were defined to support public health burden tracking, serotype and AMR monitoring, vaccine safety evaluation, and economic analyses (Table 2). During the workshop, our

Table 2 Matrix of Outcomes Identified for Large-Scale Pre- and Post-Vaccine Introduction Studies

Outcome Groups	Exposures and Outcomes Of Interest	Categories / Definitions
Maternal exposures and outcomes	Maternal colonisation	
	GBS screening	
	Maternal invasive GBS cases	
	Intrapartum antibiotic prophylaxis	
	GBS vaccine	
Pregnancy outcomes	Stillbirth	Defined as death of a fetus after 20/22/28 weeks of pregnancy
	Preterm birth	Extremely preterm (<28 GA), Very preterm (28 - <32 GA), Moderate preterm (32 - <34 GA), Late preterm (34 - <37 GA)
	Low birth weight	Defined as birth weight < 2500 gram
	Small for gestational age	Defined, for singleton pregnancies, as a dichotomous variable (yes/no) of birth weight below 2 standard deviations of sex- and gestational week-specific distributions, using country-specific reference standard.
	Small-Vulnerable-Newborns	Preterm – small for gestational age Preterm – non-small for gestational age Term – small for gestational age
Neonatal and infant outcomes	Invasive GBS disease in infants	GBS sepsis GBS meningitis Defined as isolation of GBS from a normally sterile site
	Onset of invasive GBS disease	Early onset Late onset
	Neonatal mortality	Defined as death of a liveborn within the first 28 days of life
	Infant mortality	Defined as death of an infant death between 1 day and 1 year of age
	Neonatal Intensive Care Unit admission	

(*Continued*)

Table 2 (Continued).

Outcome Groups	Exposures and Outcomes Of Interest	Categories / Definitions
Vaccine safety	Major congenital malformations	Any major congenital malformation Nervous system Eye Ear, face and neck Congenital heart defects Respiratory Orofacial clefts Gastro-intestinal Abdominal wall defects Kidney and urinary tract Genital Limb Other anomalies /syndromes
Economic outcomes	Direct costs	Hospitalizations Neonatal care Maternal care
	Indirect costs	Productivity loss Workforce participation Social benefits Long-term disability
Long-term outcomes	Neurodevelopmental impairments	Visual impairments Hearing impairments Cognitive impairments Motor impairments Emotional and behavioural impairments
	Neurological outcomes	Epilepsy and seizure disorders Cerebral palsy Hydrocephalus

Abbreviations: GA, gestational age; GBS, group B Streptococcus.

expert group developed a comparability matrix for these outcomes across the three countries and aligned on critical knowledge gaps for large-scale pre- and post-vaccine introduction studies.

Public Health Surveillance

Future maternal GBS vaccination programmes will require monitoring of maternal, fetal, and child health clinical outcomes with record linkage of vaccination data and laboratory-confirmed GBS infection data. For stillbirths, for which microbiological investigations are not always performed, high-quality registry data gathered before and after the introduction of a GBS vaccine would provide valuable insights into the impact of maternal GBS vaccination on these outcomes. Beyond the neonatal period, long-term child developmental outcomes are essential, but large cohorts are very expensive. Longitudinal individual-level combination of such data nationally could facilitate a comprehensive assessment of the effects of vaccines on a wide range of long-term outcomes, while minimising loss to follow-up and reducing costs.[3]

When maternal GBS vaccines are implemented as an addition to IAP, collecting data on both will be essential to disentangle the effects of vaccination and IAP on invasive GBS disease incidence. GBS vaccination is likely to contribute to decreased antibiotic use and diminished risk of further expansion of penicillin resistant GBS, which has been selected as a priority pathogen by WHO in addressing AMR.[19] To assess both direct vaccine effectiveness against infant invasive

GBS disease and the broader effects of maternal GBS immunisation on outcomes such as antimicrobial use and preterm births, data on risk factors and IAP use must be systematically gathered and linked to vaccination and clinical outcome data. Further, combining health data with socioeconomic factors and ethnicity data would facilitate monitoring of how vaccination access or uptake contributes to perinatal health equity.

Monitoring of Serotypes and Antimicrobial Resistance

Monitoring GBS strain characteristics after the introduction of vaccination will be essential, given the theoretical potential for strain replacement. Although both vaccine candidates entering phase III clinical trials have been predicted to have wide coverage of capsular serotype or alp protein distributions, neither has 100% coverage, thus leaving room for potential expansion of non-vaccine strains. Establishing mechanisms to monitor changes in strain characteristics, through either national or sentinel submission of clinical strains to a microbiology reference laboratory, will support understanding of evolving GBS disease patterns and improve vaccine effectiveness estimates. Given the increases in AMR to second-line agents used for IAP, and the potential of penicillin non-susceptibility, monitoring of AMR through either analysis of referred isolates or capture of routinely collected diagnostic laboratory data will also be essential in understanding post-licensure changes in disease incidence and outcomes.

Vaccine Safety Monitoring

Vaccine safety monitoring includes early detection of rare or serious adverse events following immunisation (AEFI), timely investigation of such events, implementation of risk mitigation measures, and transparent communication with the public and healthcare providers.[20] Vaccine safety monitoring during pregnancy for adverse events following maternal immunisation (AEFMI) is of particular importance to ensure that both mother and fetus do not suffer negative consequences of vaccination. As a result, maternal immunisation requires special considerations which influence the design of surveillance systems.[21] All of these actions are vital in preserving the confidence and support of healthcare communities and the general public. Signals used for vaccine safety monitoring during pregnancy include new or rare AEFMI, increased frequency of known adverse events, serious adverse events, effects on special populations (eg, miscarriage, stillbirth, birth defects or preterm births), and interactions with comorbidities or medications.

Globally, several coordinated systems are in place to monitor vaccine safety. These systems rely primarily on spontaneous reporting but are increasingly being supported by active surveillance mechanisms. For instance, the Vaccine Safety Datalink in the US links healthcare records to vaccination status to detect patterns of AEFIs. Moreover, post-authorisation safety studies are mandated by regulatory authorities after vaccine approval. National routinely collected health registry data crucially enable the identification of potential AEFIs and ensure prompt responses to any safety concerns in post-authorisation safety studies.

Economic Analyses

As new evidence emerges regarding the characteristics and health effects of GBS vaccines, updating existing health economic models will be important to ensure that cost-effectiveness estimates remain accurate and relevant to decision making.[2] Such updated analyses would provide refined estimates of the economic value of maternal GBS vaccination, to assist decision-makers in evaluating vaccine adoption, procurement, and pricing strategies. The evidence base would be further strengthened, and the estimated value of vaccination would be improved, through incorporation of post-licensure data on vaccine efficacy to accurately quantify health benefits, together with new data indicating the contribution of maternal GBS colonisation to stillbirths and preterm births.

In countries where IAP is routinely implemented, decision models must consider potential interactions between vaccination and existing risk-based or microbiological screening strategies. These models may be used to evaluate the potential for integrated prevention strategies to optimise health gains, while also decreasing antibiotic use and associated risks of AMR.

Furthermore, the availability of high-quality, combined epidemiological and demographic data would enable equity analyses exploring how socioeconomic factors influence disease burden and vaccine-preventable outcomes. Ultimately, such analyses could help inform more equitable vaccine implementation strategies.

Conclusion

As the wider burden of disease due to GBS has become clearer, including stillbirths and preterm labour, a stronger economic case can be made for greater investment in prevention.

Several shifts are needed and our *Consortium* can help to accelerate vaccine readiness for maternal immunisation through several tracks:

- *Improved measurement of burden now*: better national burden information delivered through multi-country studies examining stillbirths with microbiological diagnosis, including GBS, as well as maternal GBS disease and more data on children's long-term outcomes.
- *Better data for decision-making regarding uptake of new GBS vaccines*: use of existing data to inform national decision-making on adoption of GBS vaccines into routine schedules, including AMR and economic data.
- *Preparation for post vaccine surveillance and potential* "probe" *studies*: individual-level data across routine collection systems enabling targeted study designs to track and measure GBS-associated outcomes after vaccine roll-out, including stillbirths and preterm births.
- *Safety monitoring to support vaccine confidence*: a major learning in the past decade has been that effective vaccines can be offered but will be highly impactful only if they are accompanied by high confidence leading to high coverage. Data from such systems support early detection and investigation of AEFI and AEFMI, necessary for maintaining vaccine confidence.

Across Europe and globally, countries could benefit from maternal GBS vaccination, but this also requires development of stronger and more comparable routine data collection systems. The *GBS Vax-Ready European Consortium* welcomes others interested in joining in efforts to achieve these goals. Together we aim to contribute to evidence-based change for healthier beginnings and more hopeful futures for families worldwide.

Ethics Approval and Informed Consent

All participating countries will conduct the studies in accordance with country-specific legislation and data protection regulations. In the United Kingdom, the UK Health Security Agency is legally authorised to collect identifiable patient data without consent to fulfil its public health functions, including the control and prevention of communicable diseases and identification of other risks to public health. According to Danish legislation, ethical approval and informed consent are not required for registry-based studies. The studies will be reported to the Danish Data Protection Agency. In the Netherlands study protocols will be submitted to the Centre for Clinical Expertise at the National Institute for Public Health and the Environment, to assess their compliance with the Dutch law on medical research involving human subjects. For each country, individual-level data will remain within secure national environments using appropriate technical and organisational safeguards, and only non-identifiable, aggregated data will be shared for multi-country analyses.

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Disclosure

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a member of the UK Joint Committee of Vaccination and Immunisation (JCVI) and of the WHO GBS Technical Advisory Group (GBSTAG). The authors report no other conflicts of interest in this work.

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