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EDITORIAL

Protecting newborns and infants before birth: Accelerating equitable maternal vaccine introduction in low- and middle-income countries

Each year, neonatal infections—including pneumonia, sepsis, and meningitis—cause more than 550000 newborn deaths globally, many occurring before newborns and infants can benefit from routine infant immunization.[1] Maternal immunization offers a powerful and tested solution: protecting infants before birth. The success of the maternal tetanus toxoid (TT) vaccine program bears this out: when pregnant women received at least two doses of TT vaccine, global neonatal tetanus deaths fell by 94%.[2] New maternal vaccines for Respiratory Syncytial Virus (RSV)—and potentially soon for Group B Streptococcus (GBS)—could further improve newborn and infant survival. For women, families, and their obstetricians and midwives, this early window of vulnerability is a critical time.

Prevention of infant death is a global priority but is most urgent in low- and middle-income countries (LMICs), where nearly 95% of the deaths occur and where access to alternative prevention strategies is most constrained. RSV is a major cause of viral pneumonia in young children and in LMICs, causing more than 10000 child deaths every year and the hospitalization of 1.4 million infants aged under 6 months.[3] Although long-acting monoclonal antibodies could also prevent severe RSV disease in infants, their high cost and delivery requirements will limit their introduction into LMICs in the near future. GBS, a bacterial disease, is a leading cause of neonatal sepsis, meningitis, infant death, and stillbirth; each year, GBS causes an estimated 90000 newborn and infant deaths, as well as 46000 stillbirths.[4] Prevention strategies, such as intrapartum antibiotic prophylaxis, are challenging to deliver in LMICs and are unlikely to prevent GBS-associated stillbirth or late-onset disease. Maternal vaccines are thus a key intervention to prevent both RSV and GBS disease early in life.

The health and economic case for these vaccines is strong. Global burden estimates define the scale of preventable disease, and economic analyses suggest substantial health and societal value. Estimates suggest maternal GBS vaccination would generate US$1.1–$17B in annual net monetary benefit under modeled scenarios.[5] But evidence alone will not protect newborns and infants. Maternal and newborn health programs must move from research on maternal vaccines to readiness for their introduction: strengthening delivery systems, equipping providers to recommend vaccination with confidence, and ensuring women and families have the information and support needed for informed decision-making.

Achieving that readiness means aligning the people, platforms, and systems that connect pregnant women to vaccination. However, these systems were not designed to work together: antenatal care (ANC) and routine immunization programs often sit in different departments and are sustained by different funding streams, supported by different workforces, and utilize different data systems. For new maternal vaccines to reach their intended recipients, ANC platforms need to be integrated with immunization programs. Equitable maternal immunization programs depend not only on whether maternal vaccines are available, but on whether they are introduced in ways that reach all women across health systems and all levels of care. This is why readiness must be built country by country: the barriers to maternal vaccine introduction are shaped by local governance, financing, delivery platforms, provider roles, and community trust.

The Maternal Immunization Readiness Network in Africa and Asia (MIRNA) was established to help close the gap between global vaccine development and country-led delivery. The Network currently works across nine countries in sub-Saharan Africa and South Asia, representing diverse health-system, financing, and maternal immunization contexts, but is aligned to a common goal: to ensure that countries and regions with the greatest burden of disease lead planning for their own maternal vaccine introduction. Stakeholder engagement is essential from the outset: maternal vaccine introduction cannot be designed in global policy forums alone; countries must lead the design, development, and implementation of these programs, grounded in the experiences of their obstetricians, midwives, pediatricians, immunization managers, primary and public health leaders, and pregnant women and their families.

MIRNA brings together in-country partners across Africa and Asia, and supports evidence generation, health-system readiness assessment, stakeholder engagement, demand generation strategy development, and communication to share information on maternal vaccination. Its work includes assessing the evidence on burden of RSV and GBS disease in-country, quantifying the cost of delivery of new maternal vaccines, developing vaccine demand strategies, and examining readiness across levels of care. It supports the

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development and sharing of protocols, tools, and learning that extend beyond participating MIRNA countries. At its core, MIRNA is a collaborative model, supported by adaptable resources, shared learning, and opportunities to influence global strategy through local reality.

Across these nine countries, readiness opportunities and challenges vary considerably. In Nigeria, stakeholder engagement has underscored that maternal vaccine introduction is not only a technical exercise; it is a governance and coordination challenge. Heat mapping of stakeholders has identified key groups and influential bodies whose engagement will be critical across policy, delivery, regulation, monitoring, and community trust. In Nigeria, routine immunization and antenatal care are managed through different structures, creating practical barriers for vaccine delivered through ANC but governed by immunization systems. Successful introduction will require deliberate coordination among ANC providers, Expanded Programme on Immunization (EPI) managers, primary healthcare practitioners, community health leaders, regulators, monitoring and evaluation units, and professional societies. Alignment of obstetrical, nursing, and midwifery disciplines is critical.

In Kenya, demand generation highlights that evidence alone will not ensure uptake. Pregnant women, families, and health workers need clear, culturally contextualized information about disease burden, vaccine safety, and the rationale for vaccination in pregnancy. Lessons from COVID-19 demonstrate that trust must be built before rollout, not repaired after hesitancy has taken hold in communities.[6] Trusted healthcare providers are central to this effort, but they need tools, training, and confidence to communicate consistently and respectfully to their patients and families. User-centered design workshops in Kenya are bringing together pregnant women, families, health workers, and immunization specialists to understand perspectives, identify barriers to maternal vaccine acceptable, and to co-develop solutions that are responsive to community needs.

In Pakistan, early situational analyses illustrate the need to assess readiness across state and national levels. Pakistan has experience introducing new vaccines and the policy structures to support evidence-based decision-making and yet the maternal TT program is the only maternal vaccine in the national schedule. Differences in financing, workforce, integration of ANC and immunization programs, data systems, and community engagement all shape the feasibility of future maternal vaccine introduction. Pakistan's experience reinforces a broader lesson: national policy recommendation is necessary, but it is not sufficient. The successful introduction and scale of maternal vaccines depend on health systems prepared to deliver them.

Across countries in MIRNA, one message is clear: readiness is not a checklist completed before launch,[7] it is a continuous process of alignment between evidence and policy, clinicians and communities, and financing and delivery. Translating maternal vaccine recommendations into access is critical. It is also an urgent equity challenge. This is already clear for RSV: approximately 97% of childhood RSV deaths occur in LMICs, yet the maternal RSV vaccine has been introduced only in higher-income settings. LMICs are being left behind.[8]

Pharmacovigilance is an important part of the process. Systems for monitoring safety support vaccination programs, build public confidence,[9] and support communications. Many LMICs are strengthening electronic medical records and adverse event reporting systems, but these efforts need standardization and training to support comparison, and investment to ensure quality data.

The same is true for ANC innovation. Maternal vaccine introduction can benefit from practical tools that improve gestational-age assessment, appointment reminders, data quality, and counseling. mHealth education and reminders, quality improvement approaches, strengthened ANC record-keeping, and trusted provider messaging can all support timely vaccination. Maternal vaccines will succeed when they are embedded in high-quality ANC, not added as an isolated task to already overburdened services.[10]

The International Federation of Gynecology and Obstetrics (FIGO) and the International Confederation of Midwives (ICM) call to action to support new maternal vaccination programs is urgent and must be a shared professional priority. International professional societies can support clear, evidence-based communication, disseminate learnings and guidelines through critical meetings, and support maternal vaccine delivery programs that strengthen, rather than bypass, ANC systems.

Professional societies should be engaged before, not after, policy decisions are made. Societies can contribute to curriculum development and continuing professional development, develop provider-facing communication materials, and national guideline development. They can support champions at national and subnational levels who are able to communicate with policymakers, health workers, communities, and the media; and critically, they can ensure that pregnant women's perspectives inform introduction planning. Most importantly, professional societies can advocate for maternal vaccines as part of a broader commitment to maternal and newborn health equity.

The promise of maternal immunization is profound: to protect newborns before they are born, before their first clinic visit, and before they are old enough to be protected through their own vaccines. But promise is not the same as protection; protection requires readiness. It requires that countries have the evidence, financing, systems, providers, and community trust needed to deliver vaccines to pregnant women at the right time. As new maternal vaccines move from evidence to introduction, they must reach the communities where the burden is highest. The task is to turn maternal vaccine readiness into maternal vaccine reach and to ensure that no newborn is left unprotected.

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All listed authors have been involved in the production of this FIGO editorial. All authors have contributed to the structure, drafting and analysis of data included in this editorial, have reviewed and provided feedback on draft versions of the article, and have approved

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the final version for publishing. Copies of the individual authors' comments, feedback, and reviews are available upon request.

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CONFLICT OF INTEREST STATEMENT

Anna C. Seale and Kate Fay are employees of the Gates Foundation. Hellen Barsosio, Michelle J. Groome, Shifa S. Habib, Hadiza S. Galadanci, Eve Nakabembe, and Annettee Nakimuli are Maternal Immunization Readiness Network in Africa and Asia (MIRNA) investigators and have received funding from the Gates Foundation to advance the work of MIRNA. The remaining authors have no conflicts to declare.

DATA AVAILABILITY STATEMENT

Research data are not shared.

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