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Europe

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International Alliance for Biological Standardization

SCIENTIFIC WORKSHOP

8-9 june 2026 | Zurich, Switzerland

Assessing Consequences of Maternal Immunization on Foetal Outcomes

For many years, vaccination during pregnancy was avoided due to concerns of adverse events to the baby. In recent years the data on benefit to protect both the pregnant woman and her child against several infectious diseases (e.g. tetanus, pertussis, influenza and COVID-19) have been convincing, leading to routine recommendations. Respiratory Syncytial Virus (RSV) is a major pathogen with substantial morbidity and mortality. Early attempts at vaccination of young infants with an inactivated vaccine resulted in enhanced disease following natural infection. Two companies independently initiated Phase-3 randomized clinical trials (RCT) of candidate RSV preF vaccines in pregnant women. One of the trials was halted because of a higher risk of preterm birth in the vaccine group. The RCT of the other vaccine in pregnant women led to approval with restrictions on use in early pregnancy in some jurisdictions. Following use of this vaccine, there is convincing evidence that infant RSV disease has been reduced and the WHO and other vaccine advisory bodies have recommended its use during pregnancy. An alternative approach has been the use of monoclonal antibody against the prefusion protein.

Other candidate vaccines for use in pregnancy are under development e.g. candidate mRNA RSV, Group B Streptococcus and Zika virus vaccines. Safety of novel vaccines administered during pregnancy must be carefully assessed including possible impact on preterm birth. Some of these pathogens can cause preterm birth, so maternal vaccination might reduce preterm births.

The methods to study safety in future interventional and observational clinical studies require robust clinical data and strong statistical methods that use optimal approaches. The clinical relevance of a possible increased risk of preterm birth must be considered in a benefit-risk assessment.

In 2Q2026, IABS will hold a Workshop aiming to contribute to methodology for safety assessment of maternal vaccines. The objective is to allow clinical, medical and statistical scientists including regulatory authorities to suggest standardized assessment of the impact of maternal immunization on preterm birth. The forum will engage multiple specialists in obstetrics, pediatrics, biostatistics, vaccine developers and regulators to discuss multiple perspectives around vaccination during pregnancy. These include methods to assess gestational age, the preferred time window for vaccination, collection of clinical/medical data concerning the preterm birth (potential causes, clinical assessment of the infant,...) and the consequences of premature birth in different locales.

Scientific Committee

- Frank Vandendriessche (IABS Co-Chair of the Human Vaccines Committee, Belgium)
- Pieter Neels (IABS Co-Chair of the Human Vaccines Committee, Belgium)
- Steve Black (Global Vaccine Data Network, USA)
- Marco Cavaleri (European Medicines Agency, UK)
- Kathryn Edwards (Vanderbilt University, Medical Center, USA)
- Janet Englund (Seattle Children's Hospital, USA)
- Stephen Evans (London School of Hygiene & Tropical Medicine, UK)
- Tessa Goetghebuer (Saint-Pierre Hospital, Belgium)
- Jennifer Griffin (Global Vaccine Data Network, USA),
- David Kaslow (CBER FDA, USA)
- Isabel Leroux-Roels (Gent University, Belgium)
- Arnaud Marchant (Faculty of Medicine ULB, Belgium)
- Kirsten Maertens (Antwerpen University, Belgium)
- Pierrette Melin (Liege University, Belgium)
- Flor Muñoz (Texas Children's Hospital, USA)
- Lidia Oostvogels (Minervax, Denmark)
- David Radley (Pfizer, USA)
- Anna Seale (Gates Foundation, UK)
- Peggy Webster (GSK, USA)
- Nina Wressnigg (CEPI, Austria)