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Respiratory syncytial virus vaccination in pregnancy – Position statement by the European board and college of obstetrics and gynaecology (EBCOG)

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ABSTRACT

The European Board and College of Obstetrics and Gynaecology (EBCOG) expresses its concerns on the morbidity associated with respiratory syncytial virus (RSV) infections in pregnant women and their infants. This position statement reviews the role of maternal vaccination against RSV during the third trimester of pregnancy to reduce the morbidity of RSV in both mother and child. The EBCOG Standing Committee on Standards of Care and Position Statements endorses the recommendation for the administration of 120 μg of a bivalent RSV prefusion F protein–based (RSVpreF) vaccine to pregnant women early in the third trimester. This provides protection against RSV and its attendant comorbidities both to the mother and the infant. Repeat RSV vaccination in subsequent pregnancies is not recommended due to lack of data. regular targeted vaccination of pregnant women.

Introduction

Respiratory syncytial virus (RSV) is a highly contagious infection causing acute respiratory tract illness in persons of all ages and is the underlyin cause of about 22 % of all acute lower respiratory infections [1]. It can have serious consequences, particularly in high-risk patients and children aged under 5 years, being responsible for approximately 84,500–125,200 deaths per year in young children [2]. It has been estimated that in the European Union (EU-28), an annual average of 245,244 (95 % CI: 224,688–265,799) hospital admissions with a respiratory infection were associated with RSV in children aged under 5 years. 75 % of these cases occur among children aged under 1 year and 37 % occuring in infants aged less than 2 months. The estimated incidence of RSV admissions in the EU-28 region was reportedly 71.6 per 1000 in infants aged under 2 months with the rates declining as the children grew older (3–5 months: 38.9; 6–11 months: 17.6; 12–35 months: 5.0; 36–59 months: 1.0) [3]. It has further been shown that RSV-RTI hospital admissions of children under five years accounted for 9.9–21.2 bed days per 1000 children annually with about 70 % of these bed days being accounted for in infants aged less than one year. [4]. RSV infection in early childhood can be associatred with long-term respiratory morbidity, such as decreased lung function and recurrent wheezing, which can persist into early adulthood. The long-term effects contribute to decreased quality of life and increased healthcare resource utilization [5]. The age-specific mortality rate from RSV in the U.S.A. has been estimated at 1.2 per 100,000 population in infants aged less than 1 year [6].

While the primary concern of RSV targets infants and early childhood, pregnant women with RSV infection have been reported to be at an increased risk of preterm delivery and more severe short-term morbidity particularly more severe respiratory complications and other morbidities such as septic shock, coagulopathy, acute heart failure, and acute renal failure [7]. It must be appreciated that respiratory physiology during pregnancy, especially in the third trimester, gives rise to a low expiratory reserve volume mainly caused by the upwards displacement of the abdominal organs by the enlarging pregnancy unit. Because of the RSV-associated morbidity in both the mother and infant, it is pertinent to consider adoping preventive strategies to address the issue. The available strategies to address RSV infection include maternal vaccination with RSVPreF (Abrysvo) and immunoprophylaxis of the

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newborn.

Maternal vaccination with RSVPreF

In a randomized phase 3 double-blind trial, conducted in 18 countries, pregnant women at 24–36 weeks gestation were randomised to receiving a single intramuscular injection of 120 μg of a bivalent RSV prefusion F protein–based (RSVpreF) vaccine or placebo (vaccine: 3682 | placebo: 3676 women). Maternal vaccination was found to be effective in reducing medically-attended severe RSV-associated lower respiratory tract illness in infants with no safety concerns being identified. Vaccine efficacy within 90 days after birth was 81.8 %, while within 180 days, efficancy was reported to be 69.4 % [8]. The incidence of severe events within 1 month in this study was similar in the vaccine group (13.8 %) and the placebo group (13.1 %). Serious adverse events were reported in the vaccine group included pain in an arm followed by bilateral lower-extremity pain, premature labor, systemic lupus erythematosus, eclampsia and premature placental separation in the placebo group [8,9].

While other studies have observed an excess in preterm births in vaccinated women, the overall non-statistically significant imbalance was observed in trial sites located in two upper-middle-income countries, but not in other settings [10,11]. In contrast, a cohort study of pregnant individuals delivering at 32 weeks' gestation or later proved that the RSVpreF vaccine was not associated with an increased risk of pretern deliveries or other adverse perinatal outcomes [12]. While other RSV vaccines are approved for other populations, RSVPreF (Abrysvo) is the only RSV vaccine approved in pregnancy [13]. Walsh et al. reported the safety of a bivalent RSV prefusion F vaccine in older adults. The same incidence of the adverse events were reported in the vaccine and placebo groups – 2.3 % and three of these events were considered by the investigators to be related to the trial intervention – a delayed allergic reaction 7 h after injection of RSVpreF vaccine, with recovery on the same day; a combination of diplopia, paresthesia of palms and soles, and oculomotor and abducens nerve paralysis 8 days after injection in a participant in the vaccine group who had a medical history of diabetes mellitus; and a myocardial infarction that developed 6 days after injection [14].

The WHO Strategic Advisory Group of Experts (SAGE) on Immunization recommends that all countries should introduce passive immunization for the prevention of severe RSV disease in young infants using a single dose of vaccine in the third trimester of pregnancy [10]. At least 14 days are needed from the time of maternal vaccination for development and transplacental transfer of maternal antibodies [15]. The studies suggest the RSV vaccine can be effectively and safely coadministered with the diphtheria, tetanus, and acellular pertussis vaccine [16]. RSVpreF vaccine is now licensed for use in pregnant individuals to help protect infants in more than 40 countries around the world and the national/regional RSV vaccination recommendations for pregnant individuals to protect infants had been endorsed [17,18,19,20].

The European Board & College of Obstetrics and Gynaecology endorses the recommendation for the administration of 120 μg of a bivalent RSV prefusion F protein–based (RSVpreF) vaccine to pregnant women early in the third trimester. This provides protection against RSV and its attendant comorbidities both to the mother and the infant. Repeat RSV vaccination in subsequent pregnancies is not recommended due to lack of data. Until evidence-based studies do confirm a role for repeat vaccination in a subsequent pregnancy, infants born to mothers vaccinated during a previous pregnancy should receive the injectable monoclonal antibody nirsevimab for the prevention of RSV. In a pragmatic trial, nirsevimab vaccination of infants under 12 months of age entering their first RSV season, was shown to protected against hospitalization for RSV-associated lower respiratory tract infection and against very severe RSV-associated lower respiratory tract infection [21]. Decisions to include maternal vaccination and/or the long-acting monoclonal antibody in an immunization programme should consider cost, financing, supply, anticipated coverage and feasibility of implementation within the existing health system [10].

Recommendations

- Offer single dose vaccination with 120 μg of a bivalent RSV prefusion F protein–based (RSVpreF) vaccine to all pregnant women at the beginning of the third trimester.
- In previously vaccinated women, offer injectable monoclonal antibody vaccination to infants before the RSV season ensues.

This position statement was approved by the EBCOG Standing committee on Standards of Care and Position Statements on 10th March 2025.

Declaration of competing interest

The authors declare that they have no known competing financial interests or personal relationships that could have appeared to influence the work reported in this paper.

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