Pregnancy outcomes following maternal vaccination with recombinant pertussis vaccines: Evidence from three observational studies in Thailand

Souad Mansouri, PhD
Director, Clinical Development
BioNet

IABS June 2026, Zurich

BioNet

Sharing Vaccine Expertise

A fully integrated vaccine organisation specialised in genetically designed vaccines since 2001

Developer of recombinant, DNA and mRNA vaccines

Manufacturer of the world's only available recombinant pertussis vaccines

Collaborations in R&D, production and distribution

250 collaborators in **Europe and Asia-Pacific**

Scientific Advisory Board

(Prof. Emeritus Stanley Plotkin)

Our Mission is to Accelerate Access to Vaccines Globally Through Innovation and Collaboration

VacPertagen

VacPertagen / Pertagen (aP5)

- *Pertussis vaccine (recombinant, acellular, component, adsorbed)*
- Two-components: 5 µg PT_{gen} + 5 µg FHA
- Licensed in EU, Thailand, Singapore

- booster immunisation against pertussis of individuals 12 years and above
- passive protection against pertussis in early infancy following maternal immunisation during pregnancy

When compared with other pertussis booster vaccines, VacPertagen:

- Contains genetically detoxified PT (PT_{gen}), compared with chemically-detoxified PT in other vaccines
- A monovalent pertussis vaccine, whereas other boosters are combined vaccines (Tdap or Tdap-IPV)
- Contains 5 µg of PT_{gen}, consistent with the antigen content used in paediatric DTaP vaccine (same 84% efficacy with DTaP containing 25 µg of PT_{chem} in a trial in infants in Italy. Greco D, 1996)

Other recombinant vaccines licensed in Asia or Latin America

- Boostagen: combined TdaP5 (high dose 5 µg PT_{gen})
- Boostagen-2: combined Tdap2 (reduced dose 2 µg PT_{gen})

BioNet

Background and Rationale

- Infants are at highest risk of severe pertussis, particularly in the first months of life before completion of primary vaccination.
- Maternal immunisation provides passive protection through transplacental transfer of antibodies.
- Maternal vaccination against pertussis is recommended in many countries to reduce morbidity and mortality in young infants.
- Real-world and clinical data contribute to the assessment of safety and effectiveness of maternal immunisation strategies.

Objectives

- To evaluate pregnancy outcomes including prematurity after maternal vaccination with a pertussis-only vaccine

- To present data from 3 observational studies

- To compare outcomes with:
  - Td vaccination
  - Background population rates

- To inform the safety profile in pregnancy

Safety Database in Pregnant Women

Post-marketing exposure

- Licensed in Asia since 2016 (VacPertagen and Td-VacPertagen)
- ~1006317 pregnant women vaccinated in Thailand (as of March 2026)

Clinical safety database

- 4687[1] pregnancy outcomes
- From randomised controlled trials and observational studies
- Including 2122[1] prospectively followed pregnancies

Safety findings

- No evidence of vaccine-related adverse effects on pregnancy outcomes or on the health of the fetus/newborn
- No safety signals identified

[1]Data on files

BioNet

Study design

Data derived from three observational studies conducted in Thailand

- **Study types included**:
  - Prospective observational study:
    - **PerMIT**[1] (pregnant women vaccinated with VacPertagen, Td–VacPertagen, or Td during pregnancy in Sep 2018 – May 2020)
  - Retrospective observational studies:
    - **PerMIS-01**[2]: Medical chart review of pregnant women (vaccination in Jan 2020-Apr 2024) at hospitals and clinics in Thailand compared with a large historical hospital cohort from Health Data Center of MoPH, Thailand during 2019-2020
    - **Pertagen-MOMS**[2]: Database review from Siriraj Women's Vaccination Center (SiWVC) pregnancy registry of VacPertagen (vaccination from 2021–2023), compared with those who received Td vaccine and have delivered at Siriraj hospital between 2007 and 2018.

- **Population**:
  - Pregnant women vaccinated with VacPertagen
  - Comparator group: pregnant women vaccinated with Td

- **Outcomes assessed**:
  - Pregnancy outcomes (including prematurity and perinatal outcomes)
  - Safety outcomes in mothers and infants

[1] Chaithongwongwatthana S, et al. Int J Infect Dis. 2024. doi: 10.1016/j.ijid.2024.107047.

[2] Data presented for PerMIS-01 and Pertagen-MOMS studies are preliminary, have not undergone peer review, and should not be cited.

Study populations

- More than 3000 pregnant women vaccinated with VacPertagen or Td-VacPertagen across three observational studies
- Comparator group: Td-vaccinated pregnant women
- Vaccination during pregnancy (routine clinical practice settings)
- Data collected from sites in Thailand

Studies included

- PerMIT (prospective study): VacPertagen = 248, Td-VacPertagen = 249 , Td =75
- PerMIS-01 (retrospective study): VacPertagen = 1980, Td (historical cohort) = 623472
- Pertagen-MOMS (retrospective study): VacPertagen =585, Td (historical cohort) = 106946

Pregnancy Outcomes (overall)

Study	Number of pregnant women (N)	Number of newborns (N)	Preterm (%)	Other Key Findings
PerMIT	572	572[a]	3.63% for VacPertagen 7.63% for Td-VacPertagen 9.33% for Td comparator	Delivery complications[c] 27.4% for VacPertagen 29.7% for Td-VacPertagen 34.7% for Td comparator
PerMIS-01	1980	1985[b]	5.69% for VacPertagen 13.25% for Td comparator	Delivery complications[d] 10.01% for VacPertagen
Pertagen-MOMS	585	585[a]	9.40% for VacPertagen 13.88% for Td comparator	The incidence of preterm delivery was similar to that in the general population at Siriraj hospital[e]

[a] All deliveries were single births.
[b] Among the 1980 pregnant women, 1976 had singleton pregnancies, 3 had twin pregnancies, and 1 had a triplet pregnancy resulting in a total of 1985 infants.
[c] Cephalopelvic disproportion was the most common delivery complication (13.3% Td; 11.7% VacPertagen ; 16.1% Td-VacPertagen).
[d] The most common complication was postpartum hemorrhage, reported in 1.87% of women, followed by meconium-stained amniotic fluid (0.86%), abnormal fetal heart rate pattern (Category II) (0.81%), gestational diabetes mellitus (non-insulin treated) and gestational hypertension (each 0.71%).
[e] The observed preterm delivery rate of 9.40% was within the range historically reported 9.4%-13.7% (Chawanpaiboon S and Kanokpongsakdi S. Siriraj Med J. 2011).

Neonatal Outcomes (overall)

Study	Healthy at Birth	Birthweight (mean)	Key Neonatal Findings
PerMIT	89.86%	3127 g	- Low birth weight: 5.24% VacPertagen / 6.43% Td-VacPertagen - Stillbirth: not collected - Congenital anomaly: not collected*
PerMIS-01	84.48%	Not collected*	- Low birth weight: 0.60% for VacPertagen - Stillbirth: 0% for VacPertagen - Congenital anomaly**: 1.51% for VacPertagen
Pertagen-MOMS	80.00%	~3052 g	- Low birth weight: 10.9% for VacPertagen versus 11.3% for Td - Stillbirth: 0% for VacPertagen - Congenital anomalies**: 2.6% for VacPertagen

*This parameter was not part of the study protocol.
**The observed rate of congenital anomaly was lower than 8.28%. (Pangkanon S, et al. J Med Assoc Thai 2014)

Preterm birth rates across studies

- Preterm birth rates
  - PerMIT: 6.1% (VacPertagen : 3.63%, Td-VacPertagen: 7.63%, Td: 9.33%)
  - PerMIS-01: 5.7%
  - Pertagen-MOMS: 9.4%

- Comparison
  - Comparable to Td-vaccinated cohorts
  - Within expected range of background population estimates

- No increase in preterm birth observed following maternal vaccination with VacPertagen

BioNet

Summary on safety

- Pregnancy Outcomes (overall)

Across three studies (around 3,000 vaccinees), pregnancy outcomes were generally reassuring.

- Preterm birth rates following VacPertagen vaccination ranged from 3.6% to 9.4% and were comparable to or lower than those observed in Td comparator cohorts (9.3%–13.9%).
- Delivery complications occurred at frequencies consistent with routine obstetric practice and showed no evidence of increased risk following VacPertagen vaccination.
- No safety signals related to pregnancy outcomes were identified across the three studies.

Summary on safety (cont.)

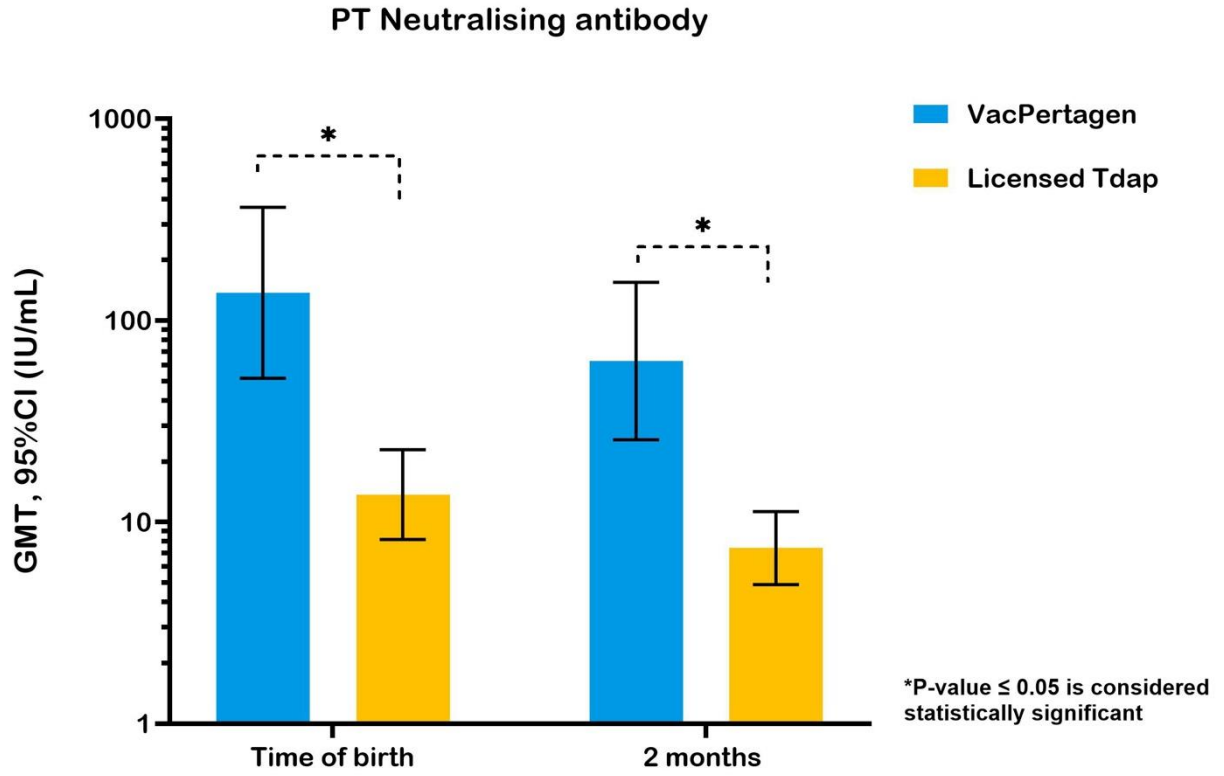
- Neonatal Outcomes (overall)

Across the PerMIT, PerMIS-01, and Pertagen-MOMS studies, neonatal outcomes were generally favorable.

- Healthy-at-birth rates ranged from 80.0% to 89.9% across the three studies.
- Mean birthweight (reported in two studies) was consistent and within expected ranges (3050-3127g).
- Low birth weight rates following VacPertagen vaccination were low overall and comparable to expected population rates.
- No stillbirths were reported among VacPertagen-exposed pregnancies in PerMIS-01 and Pertagen-MOMS.
- Congenital anomaly rates in VacPertagen-exposed infants (1.5% in PerMIS-01 and 2.6% in Pertagen-MOMS) were below the published background rate of 8.28%.
- No pattern suggestive of vaccine-related neonatal safety concerns was identified.

Immunogenicity

Transfer of higher pertussis antibodies to infant persisting at 2 months of age



Higher PT neutralising antibodies in infants at birth and 2 months of age

Reference: EPAR VacPertagen, November 2025 https://www.ema.europa.eu/en/medicines/human/EPAR/vacpertagen.

Conclusion

Overall, neonatal outcomes across the three studies indicate a reassuring safety profile.

- Most infants were healthy at birth, with birthweights within expected ranges and no evidence of major safety signals.
- Reported neonatal findings were either infrequent, non-specific, or mild and self-limited, and no consistent pattern of congenital anomalies was observed.
- Preterm birth rates remained within expected background ranges and were comparable to Td-vaccinated cohorts.
- Maternal immunisation induced strong PT-neutralising antibody responses in infants, persisting during early infancy.
- These data do not indicate clinically significant maternal or neonatal safety risks associated with vaccination with VacPertagen during pregnancy.

Acknowledgements

Siriraj Hospital
- Chenchit Pichailuck and study team

Chulalongkorn University
- Surasith Chaithongwongwatthana and study team

Data management & Statistical Analysis
- Center of Excellence for Biomedical and Public Health Informatics (BIOPHICS), Faculty of Tropical Medicine, Mahidol University
- Ngamphol Soonthornworasiri, Department of Tropical Hygiene, Faculty of Tropical Medicine, Mahidol University

BioNet
- Hong Thai Pham and Clinical Development team