Supplementary Table - Medline Search Strategy

|  |  |  |
| --- | --- | --- |
|  | Search Term | Hits |
|  | MESH Vaccines | 36456 |
|  | MESH Vaccination  | 135110 |
|  | MESH Immunization | 61354 |
|  | Vaccin\* OR immunis\* OR immuniz\* OR inoculat\*  | 273669 |
|  | 1 OR 2 OR 3 OR 4 | 1168563 |
|  | MESH Pregnancy | 267163 |
|  | MESH Mothers | 76795 |
|  | MESH Prenatal care | 42632 |
|  | MESH Maternal exposure | 16448 |
|  | Matern\* OR Mother\* OR prenat\* OR antenat\* Pregnan\* | 1719446 |
|  | 6 OR 7 OR 8 OR 9 OR 10 | 396411 |
|  | MESH "Drug-Related Side Effects and Adverse Reactions"/ | 49711 |
|  | MESH Safety/ | 50054 |
|  | MESH Risk Factors/ | 1304515 |
|  | MESH Risk Management/ | 23524 |
|  | (Adverse OR injurious OR undesirable) adj3 (event\* our outcome\* or effect\* or reaction\*) | 3115742 |
|  | Risk\* OR safety OR side effect\* or aefi\* | 5640433 |
|  | 12 OR 13 OR 14 OR 15 OR 16 OR 17 | 2408271 |
|  | 5 AND 11 AND 18 | 5764 |
|  | Line 19 Limited to (English language and humans) | 4516 |
|  | **Line 20 limited to date of the previous search**  | **3998** |

Supplementary Table - Embase Search Strategy

|  |  |  |
| --- | --- | --- |
|  | Search Term | Hits |
|  | MESH Vaccine | 103190 |
|  | MESH Vaccination  | 285205 |
|  | MESH Immunisation | 143065 |
|  | Vaccin\* OR immunis\* OR immuniz\* OR inoculat\*  | 1144390 |
|  | 1 or 2 or 3 or 4 | 1144390 |
|  | MESH Pregnancy | 757689 |
|  | MESH Mother | 149742 |
|  | MESH Prenatal care | 69981 |
|  | MESH Maternal exposure | 7686 |
|  | Matern\* OR Mother\* OR Pregnan\* OR antenat\* OR prenat\* | 2097011 |
|  | 6 or 7 or 8 or 9 or 10 | 2097011 |
|  | MESH "side effect”/ | 526369 |
|  | MESH adverse event | 142083 |
|  | MESH adverse drug reaction | 389103 |
|  | MESH Safety/ | 353261 |
|  | MESH Risk Factor/ | 1913054 |
|  | MESH Risk Management/ | 62230 |
|  | (Adverse OR injurious or undesirable) adj3 (event our outcome\* or effect\* or reaction\*) | 3053060 |
|  | Risk\* OR safety OR side effect\* or aefi\* | 9733320 |
|  | 12 or 13 or 14 or 15 or 16 or 17 or 18 or 19 | 10945476 |
|  | 5 and 11 and 20 | 27027 |
|  | English language and humans | 23136 |
|  | **Line 22 limited to the date of the previous search**  | **8369** |

Supplementary Table - Cochrane Search Strategy

|  |  |  |
| --- | --- | --- |
|  | Search Term | Hits |
|  | MESH Vaccines | 32635 |
|  | MESH Immunization | 15822 |
|  | MESH Vaccination | 8369 |
|  | Vaccin\* OR immunis\* OR immuniz\* OR inoculat\* | 96769 |
|  | 1 OR 2 OR 3 OR 4 | 97176 |
|  | MESH Pregnancy | 72226 |
|  | MESH Mothers | 6357 |
|  | MESH Prenatal care | 4915 |
|  | MESH Maternal exposure | 198 |
|  | Matern\* OR Mother\* OR Pregnan\* OR antenat\* OR prenat\* | 286709 |
|  | 6 OR 7 OR 8 OR 9 OR 10 | 287319 |
|  | MESH "Drug-Related Side Effects and Adverse Reactions"/ | 9348 |
|  | MESH Safety/ | 11463 |
|  | MESH Risk Factors/ | 77542 |
|  | MESH Risk Management/ | 19582 |
|  | Adverse OR injurious OR undesirable NEAR event\* our outcome\* or effect\* or reaction\* | 4046449 |
|  | Risk\* OR safety OR side effect\* or aefi\* | 1677723 |
|  | 12 OR 13 OR 14 OR 15 OR 16 OR 17 | 4344260 |
|  | 5 AND 11 AND 17 | 8920 |
|  | **Line 19 limited to 2014-2021** | **2685** |

Supplementary Table - Web of Science Search Strategy

|  |  |  |
| --- | --- | --- |
|  | Search Term | Hits |
| 1 | Vaccin\* or immunis\* or immuniz\* or incoulat\* | 300938 |
| 2 | Pregnan\* or mother\* or matern\* or antenat\* or prenat\* | 462808 |
| 3 | Safety or risk\* or side effect\* or aefi\* | 2973412 |
| 4 | Adverse or injurious or undesirable NEAR/3 event\* or outcome\* or effect\* or reaction\* | 8772639 |
| 5. | 3 or 4 | 10179499 |
| 6 | **Lines 1 AND 2 AND 5** | **9698** |

Supplementary Figure - PRISMA Flow-chart

Records removed *before screening*:

Duplicate records removed **(n=10013)**

Records marked as ineligible by automation tools (n=0)

Records screened

**(n =14737)**

Records excluded\*\*

**(n =14302)**

Records sought for retrieval

(**n=435)**

Records not retrieved **(n=3)**

Records assessed for eligibility

**(n=432)**

Reports excluded**: (n=256)**

Original research studies included in review

**(n =116)**

Reviews (**n=60)**

**Identification of studies via databases and registers**

**Identification**

**Screening**

**Included**

Records identified from:

Databases **(n=24750)**

Reason 1 = Pregnant women not the target population

Reason 2= Paper not in English/translatable

Reason 3= No analysis of vaccine safety as primary or secondary outcome

Reason 4 = Article is a letter, discussion, review, protocol or conference abstract

Reason 5 = No control group included

Reason 6 = Included in the previous review

Reason 7 = Another paper reporting results from study included

Reason 8 = Other

Supplementary Table - Table of included review papers.

|  |  |  |
| --- | --- | --- |
| **Number** | **Manuscript Title** | **Vaccine(s)** |
|  | Impact of Haemophilus influenzae type B (Hib) and viral influenza vaccinations in pregnancy for improving maternal, neonatal and infant health outcomes.1 | Haemophilus |
|  | Vaccines for women for preventing neonatal tetanus.2 | Tetanus |
|  | Pneumococcal vaccination during pregnancy for preventing infant infection.3 | Pneumococcus |
|  | Prophylactic vaccination against human papillomaviruses to prevent cervical cancer and its precursors.4 | Human Papillomavirus |
|  | Vaccines for preventing influenza in healthy adults. 5 | Influenza |
|  | Systematic review of the clinical development of group B streptococcus serotype-specific capsular polysaccharide-based vaccines. 6 | Group B Streptococcus |
|  | A comprehensive review of influenza and influenza vaccination during pregnancy. 7 | Influenza |
|  | Safety profile of rubella vaccine administered to pregnant women: A systematic review of pregnancy related adverse events following immunisation, including congenital rubella syndrome and congenital rubella infection in the foetus or infant. 8 | Rubella  |
|  | Safety of immunization during pregnancy: a review of the evidence of selected inactivated and live attenuated vaccines. 9 | Multiple |
|  | Safety, immunogenicity and risk-benefit analysis of rVSV-DELTAG-ZEBOV-GP (V920) Ebola vaccine in Phase I-III clinical trials across regions.10 | Ebola |
|  | Real-world evidence of quadrivalent meningococcal conjugate vaccine safety in the United States: a systematic review. 11 | Meningococcus |
|  | Safety of Tetanus, Diphtheria, and Pertussis Vaccination During Pregnancy: A Systematic Review.12 | Tetanus, Diphtheria, and Pertussis |
|  | Should expectant mothers be vaccinated against flu? A safety review.13 | Influenza |
|  | Peri-conceptional or pregnancy exposure of HPV vaccination and the risk of spontaneous abortion: a systematic review and meta-analysis. 14 | Human Papillomavirus |
|  | Fetal death and preterm birth associated with maternal influenza vaccination: systematic review. 15 | Influenza |
|  | A systematic review and meta-analysis of fetal outcomes following the administration of influenza A/H1N1 vaccination during pregnancy. 16 | Influenza |
|  | Immunogenicity, duration of protection, effectiveness and safety of rubella containing vaccines: A systematic literature review and meta-analysis.17 | Rubella |
|  | Varicella virus vaccine live: A 22-year review of postmarketing safety data. 18 | Varicella |
|  | Influenza vaccination during pregnancy: a systematic review of fetal death, spontaneous abortion, and congenital malformation safety outcomes. 19 | Influenza |
|  | Maternal vaccination against pertussis: a systematic review of the recent literature. 20 | Pertussis |
|  | Final report on exposure during pregnancy from a pregnancy registry for quadrivalent human papillomavirus vaccine. 21 | Human Papillomavirus |
|  | Maternal Influenza Vaccination and Risk for Congenital Malformations: A Systematic Review and Meta-analysis. 22 | Influenza |
|  | Safety of oral cholera vaccines during pregnancy in developing countries. 23 | Cholera |
|  | Review on the effects of influenza vaccination during pregnancy on preterm births. 24 | Influenza |
|  | An Overview of Quadrivalent Human Papillomavirus Vaccine Safety: 2006 to 2015. 25 | Human Papillomavirus |
|  | Safety of Maternal Immunization Against Pertussis: A Systematic Review. 26 | Pertussis |
|  | The safety of inactivated influenza vaccines in pregnancy for birth outcomes: a systematic review. 27 | Influenza |
|  | Literature review of vaccine-related adverse events reported from HPV vaccination in randomized controlled trials. 28 | Human Papillomavirus |
|  | Pregnancy outcomes after a mass vaccination campaign with an oral cholera vaccine: a systematic review and meta-analysis. 29 | Cholera |
|  | Pregnancy Outcomes After Human Papillomavirus Vaccination in Periconceptional Period or During Pregnancy: A Systematic Review and Meta-analysis. 30 | Human Papillomavirus |
|  | Safety and effectiveness of acellular pertussis vaccination during pregnancy: a systematic review. 31 | Pertussis |
|  | Efficacy and safety of pertussis vaccination for pregnant women - a systematic review of randomised controlled trials and observational studies. 32 | Pertussis |
|  | Risks Associated With Smallpox Vaccination in Pregnancy: A Systematic Review and Meta-analysis. 33 | Smallpox |
|  | The Effects of Influenza Vaccination during Pregnancy on Birth Outcomes: A Systematic Review and Meta-Analysis.34 | Influenza |
|  | Safety of administering live vaccines during pregnancy: A systematic review and meta-analysis of pregnancy outcomes. 35 | Mixed |
|  | Effects of maternal influenza vaccination on adverse birth outcomes: A systematic review and Bayesian meta-analysis. 36 | Influenza |
|  | Is HPV vaccination in pregnancy safe? 37 | Human Papillomavirus |
|  | Maternal influenza immunization and birth outcomes of stillbirth and spontaneous abortion: a systematic review and meta-analysis. 38 | Influenza |
|  | Yellow fever vaccine and risk of developing serious adverse events: a systematic review. 39 | Yellow fever |
|  | Safety and adverse events of prophylactic HPV vaccines among healthy women: A systematic review & meta analysis. 40 | Human Papillomavirus |
|  | Rabies post-exposure prophylaxis: A systematic review on abridged vaccination schedules and the effect of changing administration routes during a single course. 41 | Rabies |
|  | Adverse events associated with the use of recommended vaccines during pregnancy: An overview of systematic reviews 42 | Mixed |
|  | One "misunderstood" health issue: demonstrating and communicating the safety of influenza a vaccination in pregnancy: a systematic review and meta-analysis. 43 | Influenza |
|  | Quadrivalent HPV vaccine safety review and safety monitoring plans for nine-valent HPV vaccine in the United States. 44 | Human Papillomavirus |
|  | Efficacy and safety of prophylactic HPV vaccines. A Cochrane review of randomized trials. 45 | Human Papillomavirus |
|  | Influenza vaccination during pregnancy: A systematic review of effectiveness and safety. 46 | Influenza |
|  | Systematic review and meta-analysis of the effect of pertussis vaccine in pregnancy on the risk of chorioamnionitis, non-pertussis infectious diseases and other adverse pregnancy outcomes. 47 | Pertussis |
|  | Vaccines for preventing influenza in healthy children. 48 | Influenza |
|  | Maternal influenza and pregnancy outcomes-a systematic review of comparative studies49 | Influenza |
|  | Immunity after COVID-19 vaccination in people with higher risk of compromised immune status: a scoping review. 50 | SARS-CoV-2 |
|  | Maternal vaccination-current status, challenges, and opportunities. 51 | Mixed |
|  | Effectiveness and safety of COVID-19 vaccine in pregnant women: a systematic review with meta-analysis. 52 | SARS-CoV-2 |
|  | Complications of COVID-19 Vaccines during Pregnancy; a Systematic Review. 53 | SARS-CoV-2 |
|  | Is it safe and effective to administer COVID-19 vaccines during pregnancy? A systematic review and meta-analysis. 54 | SARS-CoV-2 |
|  | The consequences of COVID-19 and its vaccine on pregnant and lactating mothers. 55 | SARS-CoV-2 |
|  | COVID-19 vaccination in pregnancy. 56 | SARS-CoV-2 |
|  | COVID-19 Vaccination and Pregnancy. 57 | SARS-CoV-2 |
|  | COVID-19 vaccines in pregnancy. 58 | SARS-CoV-2 |
|  | Peripartum Outcomes Associated With COVID-19 Vaccination During Pregnancy A Systematic Review and Meta-analysis. 59 | SARS-CoV-2 |
|  | The impact of maternal SARS-CoV-2 infection and COVID-19 vaccination on maternal-fetal outcomes. 60 | SARS-CoV-2 |

Supplementary Table - Reported events specific to pregnancy or infancy with no standardised GAIA definition.

|  |  |  |
| --- | --- | --- |
| Outcome | Studies reporting cases | Number of reported cases in vaccinees |
| Caesarean or instrumental delivery | 8 | 50713 |
| Hospital admissions | 20 | 39608 |
| Neonatal jaundice | 2 | 17166 |
| Low APGAR scores | 16 | 6534 |
| Serious adverse event/adverse event/adverse event of special interest (totals) | 16 | 2747 |
| Macrosomic baby | 3 | 2020 |
| Autism/Autism Spectrum Disorder or Attention Deficit Hyperactivity Disorder | 4 | 1609 |
| Transient tachypnoea of the newborn | 2 | 974 |
| Prolonged or pre-labour rupture of membranes | 4 | 678 |
| Induction of labour | 4 | 676 |
| Mechanical ventilation | 5 | 573 |
| Peripartum fever | 4 | 525 |
| Anaemia | 3 | 287 |
| Pulmonary hypertension | 1 | 250 |
| Infections | 12 | 181 |
| Term delivery | 1 | 109 |
| Termination of pregnancy | 7 | 83 |
| Neonatal resuscitation | 1 | 58 |
| Lactation disorder | 1 | 55 |
| Perinatal death | 3 | 32 |
| Thrombocytopaenia or HELLP | 6 | 27 |
| Meconium aspiration | 3 | 15 |
| Oligohydramnios | 5 | 5 |
| Malpresentation | 3 | 2 |
| Other outcome | 26 | 218 |
| Total |  | **125145** |

Supplementary Table – Gestational-age thresholds for stillbirth in studies that reported cases in the investigational or vaccinee groups.

|  |  |
| --- | --- |
| Stillbirths (n=39) | Number (%) |
| ≥ 20 weeks’ gestation | 9 (23.1) |
| ≥ 20 weeks’ gestation or ≥ 400g | 1 (2.6) |
| > 20 weeks’ gestation | 2 (5.1) |
| ≥ 21 weeks’ gestation | 1 (5.1) |
| ≥ 22 weeks’ gestation | 4 (10.3) |
| > 22 weeks’ gestation | 1 (2.6) |
| ≥ 23 weeks’ gestation | 1 (2.6) |
| > 23 weeks’ gestation | 1 (2.6) |
| ≥ 24 weeks gestation | 1 (2.6) |
| > 24 weeks gestation | 1 (2.6) |
| 180 days amenorrhoea | 1 (2.6) |
| ≥ 28 weeks’ gestation | 2 (5.1) |
| >28 weeks’ gestation | 1 (2.6) |
| Brighton Collaboration definition used | 1 (2.6) |
| No gestational age threshold published | 12 (30.8) |
| Total | **39 (100)** |

Supplementary Table - Gestational-age thresholds for preterm birth in studies that reported cases in the interventional group or vaccinees.

|  |  |
| --- | --- |
| Preterm birth (n=68) | Number (%) |
| <37 weeks’ gestation | 50 (73.5) |
| < 35 weeks’ gestation | 1 (1.5) |
| < 36 weeks’ gestation | 1 (1.5) |
| >20 weeks and <37 weeks’ gestation | 2 (2.9) |
| >20 weeks, >400g and <37 weeks’ gestation | 1 (1.5) |
| ≥22 weeks to 37 weeks’ gestation | 1 (1.5) |
| ≥24 weeks to 37 weeks’ gestation | 1 (1.5) |
| <37+6 weeks | 1 (1.5) |
| No specific threshold defined in the publication | 10 (14.7) |
| Total | **68** |

Supplementary Table - Key information about the randomised controlled trials included in the review.

|  |  |  |  |  |
| --- | --- | --- | --- | --- |
| Author | Year of publication | Country | Vaccine | Brand and/or formulation |
| \*Binks et al61McHugh et al62 | 20152020 | Australia | Pneumococcal | 23vPPV ﻿PNEUMOVAX® 23 |
| Barug et al63 | 2019 | Netherlands | TDaP | ﻿Boostrix |
| Tapia et al64 | 2016 | Mali | Influenza | ﻿Vaxigrip |
| Madhi et al65 | 2020 | Argentina, Australia, Chile, Bangladesh, South Africa, The Philippines, Mexico, Spain, UK, USA | RSV | ﻿RSV F vaccine |
| Donders et al66 | 2016 | Belgium, Canada | GBS | Trivalent CRM﻿197- conjugated GBS vaccine |
| Munoz et al67 | 2019 | USA | RSV | RSV F |
| \*Steinhoff et al68Kozuki69 | 2017 | Nepal | Influenza | ﻿Vaxigrip  |
| Nunes et al70 | 2020 | South Africa | Influenza | ﻿Vaxigrip  |
| Madhi et al71 | 2016 | South Africa | GBS | ﻿Non-adjuvanted trivalent GBS vaccine |
| Perrett et al72 | 2020 | Australia, Canada, Czech Repblic, Finland, Italy, Spain | TDaP | Boostrix |
| Swamy et al73 | 2020 | USA | GBS | Trivalent |
| Munoz et al74 | 2020 | USA | Influenza | IIV3 (Agriflu/Fluzone/Fluarix), ﻿Sanofi Pasteur Inc, ﻿GlaxoSmithKline Biologicals, |
| Hoang et al75 | 2016 | Vietnam | TDaP | ﻿Adacel® |
| Kotinov et al76 | 2018 | Russia | Influenza | Agrippal, Grippol-Plus |
| ﻿Wanlapakorn et al77 | 2018 | Thailand | TDaP | Boostrix |
| Vesikari et al78 | 2020 | Finland | Influenza | IIV4 |
| ﻿Simões et al79 | 2019 | South Africa | Influenza | IIV3 ﻿Vaxigrip |
| Skipetrova et al80 | 2018 | Mixed | Dengue  | ﻿CYD-TDV |
| Villareal Perez81 | 2017 | Mexico | TDaP |  |
| Halperin et al82 | 2018 | Canada | Tdap | Not specified |
| Munoz et al83 | 2018 | USA | Influenza & H1N1 | Fluzone or Fluarix  |
| Weinberg et al84 | 2021 | Brazil | Pneumococcal | PCV10 & PCV23 |

\*Two studies included reporting on one trial – considered together for description of safety reporting.

1. Salam RA, Das JK, Dojo Soeandy C, Lassi ZS, Bhutta ZA. Impact of Haemophilus influenzae type B (Hib) and viral influenza vaccinations in pregnancy for improving maternal, neonatal and infant health outcomes. Cochrane Database Syst Rev [Internet]. 2015;(6):CD009982. Available from: http://ovidsp.ovid.com/ovidweb.cgi?T=JS&PAGE=reference&D=med12&NEWS=N&AN=26059051

2. Demicheli V, Barale A, Rivetti A. Vaccines for women for preventing neonatal tetanus. Cochrane Database Syst Rev [Internet]. 2015;(7):CD002959. Available from: http://ovidsp.ovid.com/ovidweb.cgi?T=JS&PAGE=reference&D=med12&NEWS=N&AN=26144877

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4. Arbyn M, Xu L, Simoens C, Martin-Hirsch PP. Prophylactic vaccination against human papillomaviruses to prevent cervical cancer and its precursors. Cochrane Database Syst Rev [Internet]. 2018;5:CD009069. Available from: http://ovidsp.ovid.com/ovidweb.cgi?T=JS&PAGE=reference&D=med15&NEWS=N&AN=29740819

5. Demicheli V, Jefferson T, Ferroni E, Rivetti A, Di Pietrantonj C. Vaccines for preventing influenza in healthy adults. Cochrane Database Syst Rev [Internet]. 2018;2:CD001269. Available from: http://ovidsp.ovid.com/ovidweb.cgi?T=JS&PAGE=reference&D=med15&NEWS=N&AN=29388196

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8. Mangtani P, Evans SJW, Lange B, Oberle D, Smith J, Drechsel-Baeuerle U, et al. Safety profile of rubella vaccine administered to pregnant women: A systematic review of pregnancy related adverse events following immunisation, including congenital rubella syndrome and congenital rubella infection in the foetus or infant. Vaccine [Internet]. 2020;38(5):963–78. Available from: http://ovidsp.ovid.com/ovidweb.cgi?T=JS&PAGE=reference&D=medl&NEWS=N&AN=31839467

9. Keller-Stanislawski B, Englund JA, Kang G, Mangtani P, Neuzil K, Nohynek H, et al. Safety of immunization during pregnancy: a review of the evidence of selected inactivated and live attenuated vaccines. Vaccine [Internet]. 2014;32(52):7057–64. Available from: http://ovidsp.ovid.com/ovidweb.cgi?T=JS&PAGE=reference&D=med11&NEWS=N&AN=25285883

10. Bache BE, Grobusch MP, Agnandji ST. Safety, immunogenicity and risk-benefit analysis of rVSV-DELTAG-ZEBOV-GP (V920) Ebola vaccine in Phase I-III clinical trials across regions. Future Microbiol [Internet]. 2020;15:85–106. Available from: http://ovidsp.ovid.com/ovidweb.cgi?T=JS&PAGE=reference&D=medl&NEWS=N&AN=32030996

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