

Algorithms to identify major congenital malformations in routinely collected healthcare data: A systematic review

Drug Safety

Melanie H. Jacobson^{1*}, Meritxell Sabidó², Ana Sofia Afonso³, Adebola Ajao⁴, Eman A. Alghamdi⁵, Susan E Andrade⁶, Dimitri Bennett⁷, Vineetkumar Kharat⁸, Marie-Laure Kürzinger⁹, Maryline Le Noan-Lainé¹⁰, Ditte Mølgaard-Nielsen¹¹, Gayle Murray¹, Elena Rivero-Ferrer¹², Sandra Lopez-Leon^{8,13}

¹ Global Epidemiology, Johnson & Johnson, Titusville, NJ, USA

² Patient Focused Real World Evidence, Merck Healthcare KGaA, Darmstadt, Germany

³ Global Patient Safety, Eli Lilly BV, Utrecht, the Netherlands

⁴ United States Food and Drug Administration, MD, USA

⁵ Saudi Food and Drug Authority, Riyadh, Saudi Arabia

⁶ Department of Population Medicine, Harvard Medical School and Harvard Pilgrim Health Care Institute, Boston, MA, USA

⁷ Global Evidence and Outcomes, Takeda Development Center Americas, Inc. Cambridge, MA, USA

⁸ Global Drug Development, Novartis Pharmaceuticals Corporation, East Hanover, NJ, USA

⁹ Global Epidemiology and Benefit Risk, Patient Safety & Pharmacovigilance, Sanofi, Gentilly, France.

¹⁰ Global Patient Safety, Eli Lilly, Cork, Ireland

¹¹ Global Safety, Novo Nordisk, Søborg, Denmark

¹² Pharmacoepidemiology and Risk Management, RTI Health Solutions, Barcelona, Spain

¹³ Rutgers Center for Pharmacoepidemiology and Treatment Science, Rutgers University, New Brunswick, New Jersey, USA

*Corresponding author: mjacob17@its.jnj.com

Supplemental Table 1. Algorithms for MCM among claims databases in USA, 2010-2025								
Author, Year	Country	Data source name	Case ascertainment denominator	Timing of MCM assessment	Algorithm rules	Coding system ^a	Code location in manuscript	Prevalence of the MCM in unexposed or general population
Feldman 2016 [1]	Canada	Administrative databases from the province of Quebec	Live births or stillbirths	Birth through 1 year of life	≥1 code	ICD 9, ICD 10	Methods	2.9%
Kröger 2021 [2]	Germany	Allgemeine Ortskrankenkasse	Live births	Birth through 1 year of life	≥1 code	ICD-10	Results, Table 1	0.5%
Brogly 2017 [3]	Canada	Canadian Institute for Health Information	Live births	NR	≥1 code	ICD-10 and CCI intervention codes	eAppendix	7.6%

Hall, 2023 [5]	USA	Department of Defense Birth and Infant Health Research program	Live born singleton infants	Birth through 1 year of life	1 inpatient record or 2 outpatient records on different days	ICD-9	Supplemental Material	1.9-3.5%
Bukowinski, 2020 [6]	USA	Department of Defense Birth and Infant Health Research program	Live born singleton infants	Birth through 1 year of life	Categories of birth defects required relevant diagnoses in the first year of life, either on one inpatient record or two outpatient records on different days	ICD-9-CM, ICD-10-CM	Supplemental Table 1	Not reported
Hall, 2020 [7]	USA	Department of Defense Birth and Infant Health Research program	Live born singleton infants	Birth through 1 year of life	Relevant diagnoses in the first year of life, either on one inpatient record or two outpatient records on different days.	ICD-9-CM, ICD-10-CM	Supplemental Table 1	3.0%
Conlin, 2017 [8]	USA	Department of Defense Birth and Infant Health Registry	Live born infants	Birth through 1 year of life	One inpatient record or two outpatient records on different days, within the first year of life	ICD-9-CM	Methods	3.7%
Bukowinski, 2012 [9]	USA	Department of Defense Birth and Infant Health Registry	Live born infants	Birth through 1 year of life	Not reported	ICD-9-CM	Methods	3.4%
Conlin, 2012 [10]	USA	Department of Defense Birth and Infant Health Registry	Live born Infants	Birth through 1 year of life	Not reported	ICD-9-CM	Methods	3.7%
Meyer, 2025 [11]	France	EPI-MERES	Live births with data through 1 year of life	Birth through 1 year of life	Differed by MCM, specified in Supplemental Table 4	ICD-10	Supplemental Table 4	No unexposed group
Wen, 2017 [12]	USA	Florida Medicaid and Florida Hospital Discharge Inpatient and Outpatient data	Singleton live births	Birth through 1 year of life	≥1 inpatient or outpatient claim during first 365 days of life	ICD-9-CM	Supplemental Material	10.5%
Reinold, 2023 [13]	Germany	German Pharmacoepidemiological Research Database (GePaRD)	Live births	Birth through 1 year of life	≥1 code in the first year of life and subsequent patient profile review considering all information (codes for diagnoses, procedures and services, drug dispensation) available until end of follow-up	ICD-10	Supplemental Material	Not specified
Platzbecker 2022 [14]	Germany	German Pharmacoepidemiological Research Database (GePaRD)	Live births	Birth through 1 year of life	≥1 code	ICD-10-GM	Methods	Not reported
Rowe, 2025 [15]	USA	MarketScan Commercial Database and Multi-State Medicaid	Singleton live births	Birth through 1 month of life	≥1 ICD-10 code in infant outpatient or inpatient records	ICD-10-CM; ICD-10-PSC; CPT codes	Table 2S	1.60%
Cesta, 2024 [16]	USA	MarketScan	Singleton and multiple live births	Infant: Birth through 3 months of life; Mother: Delivery through 1 month postpartum	The outcome is considered present if there are ≥ 2 dates with a code for the malformation group/subgroup OR ≥ 1 date with a code for the malformation group/subgroup and an outcome-specific procedure code OR ≥ 1 date with a code for the malformation group/subgroup	ICD-9 and ICD-10	Supplemental Table 4	3.8%

					and the infant died within the first 90 days. The outcome is considered maternal if there is ≥ 1 date with a code of interest in the maternal records between LMP and LMP+105 AND there are no codes in the infant record between DOB and DOB+90.			
Bernardo, 2023 [17]	USA	MarketScan	Infants admitted to NICU	Birth through 1 month of life	≥ 1 code	ICD-9 and ICD-10	Supplement	No unexposed group
Peace, 2023 [18]	USA	MarketScan	Preterm infants who had NICU birth admission	Birth through 1 year of life	≥ 1 code	ICD-9-CM, ICD-10-CM	Supplemental Table 1	Not reported
Suarez, 2022 [19]	USA	MarketScan	Live born singleton infants	Delivery through first 6 months of life	≥ 1 code	ICD-10-CM	Methods	Not reported
Zambelli-Weiner, 2019 [20]	USA	MarketScan	Live born infants	Birth through 1 year of life	≥ 1 code	ICD-9-CM	Methods, Supplemental Table 1	3.1%
Grosse, 2017 [21]	USA	MarketScan	Preterm infants	Birth through 1 year of life	≥ 1 inpatient claims or ≥ 2 claims in any setting at least 7 days apart	ICD-9-CM	Supplemental Table 4	2.3%
Jovanović, 2015 [22]	USA	MarketScan	Deliveries	Not stated	≥ 1 code	ICD-9-CM	Appendix 3	6.0%
Korelitz, 2013 [23]	USA	MarketScan	Live births	Birth through 1 year of life	≥ 1 code	ICD-9-CM	Methods, Supplemental Table 2	5.9%
Chiu, 2024 [24]	USA	Medicaid health care administration database	Linked live births	Birth through 3 months of life	≥ 2 inpatient or outpatient diagnostic codes or a diagnostic code and a corrective surgical procedure in infant claims during the 90 days after birth or in maternal claims during the 30 days after delivery	ICD-9 and ICD-10	Supplemental Table 1	No unexposed group
Straub, 2024 [25]	USA	Medicaid Analytic eXtract (MAX)	Linked live births	Infant: Birth through 3 months of life; Mother: Delivery through 1 month postpartum	Outcome is considered present if any of the following is present: ≥ 2 dates with a code for a malformation within the group, ≥ 1 date with a code for the malformation within the group and a specific procedure code, and ≥ 1 date with a code for a malformation within the group and infant death. . If codes are identified in the maternal record between LMP and LMP+105 days AND there are no codes in the infant record between DoB and DoB+90 days (i.e., only maternal codes between delivery and delivery+30), the defect is considered a pre-existing maternal defect and is not counted as an infant defect.	ICD-9 and ICD-10	Supplemental Table 1	5.0%

Bröms, 2023 [26]	USA	Medicaid Analytic eXtract (MAX)	Live born infants	Birth through first 3 months of life	≥2 diagnoses or 1 diagnosis followed by corrective surgery identified from procedure codes, or 1 diagnosis if the infant died within 3 months	ICD-9 and CPT-4	Supplemental Table 1	3.5%
Huybrechts, 2022 [27]	USA	Medicaid Analytic eXtract (MAX)	Live born infants	Delivery to 3 months after delivery (infant); delivery to 30 days after delivery (mother)	Malformation was considered present if: >1 date with a code indicating a malformation or, 1 date with a code indicating a malformation and a specific surgery code for the correction of a malformation, or 1 date with a code indicating a malformation and infant death in the first 90 days. If there was a code for the malformation group in the maternal records between LMP and LMP+105 and there were no codes in the infant record between delivery and delivery+90, then the malformation was considered maternal and the infant was considered unaffected.	ICD-9	Supplemental Table 2 and Supplemental Table 3	2.7%
Bateman, 2021 [28]*	USA	Medicaid Analytic eXtract (MAX) and MarketScan	Live born infants	Delivery to 3 months after delivery (infant); delivery to 30 days after delivery (mother)	Infant record between date of birth and DoB+90 days and/or in the maternal record between delivery and delivery+30 days, using both in- and out-patient data. Require ≥ 2 dates with a code for the malformation group/subgroup or ≥ 1 date with a code for the malformation group/subgroup and malformation-specific procedure or ≥ 1 date with a code for the malformation group/subgroup and infant died. If codes identified in the maternal record between LMP and LMP+105 AND there are no codes in the infant record between DoB and DoB+90 days (i.e., only maternal codes between delivery and delivery+30), the defect is considered a pre-existing maternal defect.	ICD-9-CM	Supplemental Table 2	3.4%
Patomo, 2020 [29]	USA	Medicaid Analytic eXtract (MAX)	Live born infants	Delivery to 3 months after delivery (infant); delivery to 30 days after delivery (mother)	A specific malformation was deemed to be present if (i) an ICD-9 diagnosis for the specific malformation group was recorded on >1 date, (ii) a diagnosis on one date was accompanied by a relevant surgery or procedure code,	ICD-9-CM	Supplemental Table 1	3.3%

					or (iii) a diagnosis was present on one date and the infant died within 90 days from birth.			
Huybrechts, 2020 [30]	USA	Medicaid Analytic eXtract (MAX)	Live born infants	Delivery to 3 months after delivery (infant); delivery to 30 days after delivery (mother)	Malformation was considered present if: >1 date with an ICD-9 code indicating a malformation or, 1 date with an ICD-9 code indicating a malformation and a specific surgery code for the correction of a malformation, or 1 date with an ICD-9 code indicating a malformation and infant death in the first 30 days. If there was a code for the malformation group in the maternal records between 90 days prior to the LMP and LMP+105 and there were no codes in the infant record between delivery and delivery+90 (i.e., the outcome was defined based on maternal codes between delivery and delivery+30), then the malformation was considered maternal and the infant was considered unaffected.	ICD-9-CM	Supplemental Table 1	3.7%
Zhu, 2020 [31]	USA	Medicaid Analytic eXtract (MAX)	Live born infants	Birth through first 3 months of life	Based on inpatient and outpatient diagnoses and procedure codes from ICD-9-CM in the maternal and infant records within the first month and three months after delivery, respectively. A specific malformation was considered to be present if there was: (i) an ICD-9 diagnosis recorded for the specific malformation on more than one date, (ii) a diagnosis on one date as well as a relevant surgery or procedure code, or (iii) a diagnosis on one date and death of the infant within 90 days of birth.	ICD-9-CM	Supplemental Table 3	3.3%
He, 2020 [32]*	USA	Medicaid Analytic eXtract (MAX)	Live born infants	Delivery to 3 months after delivery (infant); delivery to 30 days after delivery (mother)	In inpatient or other therapy infant claims from delivery to delivery + 90 days and/or maternal claims from delivery to delivery + 30 days, a. If ≥ 2 dates with an ICD-9-CM diagnostic code for the malformation group (see codes below), or b. If ≥ 1 date with an ICD-9-CM diagnostic code for the malformation group and a relevant surgery/procedure code for the	ICD-9-CM	Table 1 and Table 2	3.1%

					correction of the malformation, or c. If ≥ 1 date with an ICD-9-CM diagnostic code for the malformation group and infant death within 30 days of delivery. If the malformation is identified based on codes in maternal claims only and there is ≥ 1 date with an ICD-9-CM diagnostic code for the malformation group from last menstrual period (LMP) - 90 days to LMP + 105 days, the malformation is assumed to be maternal and the infant is unaffected.			
Huybrechts, 2018 [33]	USA	Medicaid Analytic eXtract (MAX)	Live born infants	Delivery to 3 months after delivery (infant); delivery to 30 days after delivery (mother)	Malformation was considered present if: >1 date with an ICD-9 code indicating a malformation or, 1 date with an ICD-9 code indicating a malformation and a specific surgery code for the correction of a malformation, or 1 date with an ICD-9 code indicating a malformation and infant death in the first 30 days. If there was a code for the malformation group in the maternal records between 90 days prior to the LMP and LMP+105 and there were no codes in the infant record between delivery and delivery+90 (i.e., the outcome was defined based on maternal codes between delivery and delivery+30), then the malformation was considered maternal and the infant was considered unaffected.	ICD-9-CM	Supplemental Table 2	3.1%
Huybrechts, 2017 [34]	USA	Medicaid Analytic eXtract (MAX)	Live births	Birth through first 3 months of life	1) an ICD-9 diagnosis code on more than one date; 2) a diagnosis as well as a relevant surgery or procedure code; or 3) a diagnosis code and death of infant within 90 days of birth. If the malformation was identified using codes from the maternal record alone and these codes were also present during the first 105 days of pregnancy, the outcome was excluded under the assumption that it reflected a pre-existing malformation in the mother.	ICD-9-CM	Supplemental Table 1	3.5%

Bateman, 2017 [35]	USA	Medicaid Analytic eXtract (MAX)	Live births	Pregnancy through first 3 months of infant life	1) an ICD-9-CM diagnosis code on at least 2 different dates in infant's inpatient or outpatient records or maternal records; 2) diagnosis on 1 date if infant died or underwent a corrective surgical procedures in infant's inpatient or outpatient records or maternal record	ICD-9-CM	Appendix 2	3.3%
Huybrechts, 2016 [36]	USA	Medicaid Analytic eXtract (MAX)	Live born infants	Birth through first 3 months of life	Inpatient or outpatient diagnoses and procedure codes from ICD-9 in the maternal (first month after delivery) or infant (first 3 months after date of birth) record. (1) an ICD-9 diagnosis was recorded for the specific malformation on more than 1 date, (2) a diagnosis was recorded on 1 date as well as a relevant surgery or procedure code, or (3) a diagnosis was recorded on 1 date and the infant died before 90 days.	ICD-9	Methods, Supplemental Table 2	3.3%
Chomistek, 2023 [37]*	USA	Optum Research Database	Live born infants	Between delivery and disenrollment from the health plan or the end of the study period	Presence of at least one claim for the outcome during follow-up, based on ICD-10-CM diagnostic codes.	ICD-10-CM	Methods, Table 1	8.3%
Meserve, 2021 [38]	USA	Optum Labs Data Warehouse	Live born infants	Birth through first 3 months of life	≥2 ICD-9/10 codes for a congenital malformation of the same system in the newborn on different dates	ICD-9 and 10	Supplemental Table 1	3.5%
Carman, 2016 [39]*	USA	Optum Research Database	Live born infants	Birth through 1 year of life	Naïve algorithm: ≥1 code; final claims-based algorithm not specified but varied the frequency and timing of claims, as well as claims for corrective procedures depending on body system	ICD-9	Supplemental Material	4.7-5.7%
Wang, 2024 [40]	USA	Rhode Island Medicaid data linked to vital records	Live births	Birth through first 3 months of life	≥1 code	ICD-9-CM and ICD-10-CM	Supplemental Table 3	2.9%
Phiri, 2014 [41]*	USA	Tennessee Medicaid data linked to vital records	Live and stillborn infants	Birth through 1 year of life	Maternal diagnosis claim from delivery through 90 days postpartum; infant diagnosis claims birth through first birthday; birth certificate checkbox data; fetal death certificate; death certificate causes of death before first birthday	ICD-9-CM	Methods	3.9%

*As reported by authors in publications

*Denotes a validation study, also described in Table 2.

Abbreviations: DOB: date of birth; MCM: major congenital malformation; LMP: last menstrual period

References

- Ehrmann Feldman D, Vinet É, Bernatsky S, Duffy C, Hazel B, Meshefedjian G, et al. Birth Outcomes in Women with a History of Juvenile Idiopathic Arthritis. *J Rheumatol*. 2016 Apr;43(4):804-9.
- Kröger J, Günster C, Heller G, Jeschke E, Malzahn J, Grab D, et al. Prevalence and Infant Mortality of Major Congenital Malformations Stratified by Birthweight. *Neonatology*. 2022;119(1):41-59.
- Brogly SB, Turner S, Lajkosz K, Davies G, Newman A, Johnson A, et al. Infants Born to Opioid-Dependent Women in Ontario, 2002-2014. *J Obstet Gynaecol Can*. 2017 Mar;39(3):157-65.
- Lanning J, Magallon SM, Bukowinski AT, Gumbs GR, Conlin AMS, Hall C. Investigation of a transient increase in omphalocele prevalence in a birth cohort of TRICARE beneficiaries. *Birth Defects Res*. 2024 Feb;116(2):e2305.
- Hall C, Conlin AMS, Burrell M, Romano CJ, Bukowinski AT, Gumbs GR, et al. Health outcomes among offspring of US Coast Guard responders to the Deepwater Horizon oil spill, 2010-2011. *Occup Environ Med*. 2023 Apr;80(4):192-5.
- Bukowinski AT, Hall C, Chang RN, Gumbs GR, Marie SCA. Maternal and infant outcomes following exposure to quadrivalent human papillomavirus vaccine during pregnancy. *Vaccine*. 2020 Aug 18;38(37):5933-9.
- Hall C, Abramovitz LM, Bukowinski AT, Ricker AA, Khodr ZG, Gumbs GR, et al. Safety of tetanus, diphtheria, and acellular pertussis vaccination among pregnant active duty U.S. military women. *Vaccine*. 2020 Feb 18;38(8):1982-8.
- Conlin AMS, Seveck CJ, Gumbs GR, Khodr ZG, Bukowinski AT. Safety of inadvertent anthrax vaccination during pregnancy: An analysis of birth defects in the U.S. military population, 2003–2010. *Vaccine*. 2017 2017/08/03;35(34):4414-20.
- Bukowinski AT, DeSciscio C, Conlin AM, MA KR, Seveck CJ, Smith TC. Birth defects in infants born in 1998-2004 to men and women serving in the U.S. military during the 1990-1991 Gulf War era. *Birth Defects Res A Clin Mol Teratol*. 2012 Sep;94(9):721-8.
- Conlin AMS, DeSciscio C, Seveck CJ, Bukowinski AT, Phillips CJ, Smith TC. Birth Outcomes Among Military Personnel After Exposure to Documented Open-Air Burn Pits Before and During Pregnancy. *Journal of Occupational and Environmental Medicine*. 2012;54(6).
- Meyer A, Miranda S, Drouin J, Weill A, Carbonnel F, Dray-Spira R. Safety of Vedolizumab and Ustekinumab Compared With Anti-TNF in Pregnant Women With Inflammatory Bowel Disease. *Clin Gastroenterol Hepatol*. 2025 Jan;23(1):144-53.e22.
- Wen X, Hartzema A, Delaney JA, Brumback B, Liu X, Eggerman R, et al. Combining adverse pregnancy and perinatal outcomes for women exposed to antiepileptic drugs during pregnancy, using a latent trait model. *BMC Pregnancy Childbirth*. 2017 Jan 6;17(1):10.
- Reinold J, Kollhorst B, Temme HL, Wentzell N, Haug U. Use of Acitretin Among Girls and Women of Childbearing Age and Occurrence of Acitretin-Exposed Pregnancies in Germany. *Clin Drug Investig*. 2023 Nov;43(11):865-72.
- Platzbecker K, Wentzell N, Kollhorst B, Haug U. Fingolimod, teriflunomide and cladribine for the treatment of multiple sclerosis in women of childbearing age: description of drug utilization and exposed pregnancies in Germany. *Mult Scler Relat Disord*. 2022 Nov;67:104184.
- Rowe SL, Sullivan SG, Muñoz FM, Coates MM, Agnew B, Arah OA, et al. COVID-19 Vaccination During Pregnancy and Major Structural Birth Defects. *Pediatrics*. 2025 Apr 1;155(4).
- Cesta CE, Rotem R, Bateman BT, Chodick G, Cohen JM, Furu K, et al. Safety of GLP-1 Receptor Agonists and Other Second-Line Antidiabetics in Early Pregnancy. *JAMA Intern Med*. 2024 Feb 1;184(2):144-52.
- Bernardo J, Keiser A, Aucott S, Yanek LR, Johnson CT, Donohue P. Early Readmission following NICU Discharges among a National Sample: Associated Factors and Spending. *Am J Perinatol*. 2023 Oct;40(13):1437-45.
- Peace AE, Duchesneau ED, Agala CB, Phillips MR, McLean SE, Hayes AA, et al. Costs and recurrence of inguinal hernia repair in premature infants during neonatal admission. *J Pediatr Surg*. 2023 Mar;58(3):445-52.
- Suarez EA, Nguyen M, Zhang D, Zhao Y, Stojanovic D, Munoz M, et al. Novel methods for pregnancy drug safety surveillance in the FDA Sentinel System. *Pharmacoepidemiology and Drug Safety*. 2023 2023/02/01;32(2):126-36.
- Zambelli-Weiner A, Via C, Yuen M, Weiner DJ, Kirby RS. First trimester ondansetron exposure and risk of structural birth defects. *Reprod Toxicol*. 2019 Jan;83:14-20.
- Grosse SD, Waitzman NJ, Yang N, Abe K, Barfield WD. Employer-Sponsored Plan Expenditures for Infants Born Preterm. *Pediatrics*. 2017 Oct;140(4).
- Jovanović L, Liang Y, Weng W, Hamilton M, Chen L, Wintfeld N. Trends in the incidence of diabetes, its clinical sequelae, and associated costs in pregnancy. *Diabetes Metab Res Rev*. 2015 Oct;31(7):707-16.
- Korelitz JJ, McNally DL, Masters MN, Li SX, Xu Y, Rivkees SA. Prevalence of thyrotoxicosis, antithyroid medication use, and complications among pregnant women in the United States. *Thyroid*. 2013 Jun;23(6):758-65.
- Chiu YH, Huybrechts KF, Paterno E, Yland JJ, Cesta CE, Bateman BT, et al. Metformin Use in the First Trimester of Pregnancy and Risk for Nonlive Birth and Congenital Malformations: Emulating a Target Trial Using Real-World Data. *Ann Intern Med*. 2024 Jul;177(7):862-70.
- Straub L, Bateman BT, Hernández-Díaz S, Zhu Y, Suarez EA, Vine SM, et al. Comparative Safety of In Utero Exposure to Buprenorphine Combined With Naloxone vs Buprenorphine Alone. *Jama*. 2024 Sep 10;332(10):805-16.
- Bröms G, Hernandez-Diaz S, Huybrechts KF, Bateman BT, Kristiansen EB, Einarsdóttir K, et al. Atomoxetine in Early Pregnancy and the Prevalence of Major Congenital Malformations: A Multinational Study. *J Clin Psychiatry*. 2023 Jan 16;84(1).
- Huybrechts KF, Straub L, Karlsson P, Pazzagli L, Furu K, Gissler M, et al. Association of In Utero Antipsychotic Medication Exposure With Risk of Congenital Malformations in Nordic Countries and the US. *JAMA Psychiatry*. 2022 Dec 7.
- Bateman BT, Hernandez-Diaz S, Straub L, Zhu Y, Gray KJ, Desai RJ, et al. Association of first trimester prescription opioid use with congenital malformations in the offspring: population based cohort study. *BMJ*. 2021;372:n102.
- Paterno E, Hernandez-Diaz S, Huybrechts KF, Desai RJ, Cohen JM, Mogun H, et al. Gabapentin in pregnancy and the risk of adverse neonatal and maternal outcomes: A population-based cohort study nested in the US Medicaid Analytic eXtract dataset. *PLoS Med*. 2020 Sep;17(9):e1003322.
- Huybrechts KF, Bateman BT, Pawar A, Bessette LG, Mogun H, Levin R, et al. Maternal and fetal outcomes following exposure to duloxetine in pregnancy: cohort study. *BMJ*. 2020;368:m237.
- Zhu Y, Bateman BT, Gray KJ, Hernandez-Diaz S, Mogun H, Straub L, et al. Oral fluconazole use in the first trimester and risk of congenital malformations: population based cohort study. *BMJ*. 2020 May 20;369:m1494.

32. He M, Huybrechts KF, Dejene SZ, Straub L, Bartels D, Burns S, et al. Validation of algorithms to identify adverse perinatal outcomes in the Medicaid Analytic Extract database. *Pharmacoepidemiol Drug Saf.* 2020 Apr;29(4):419-26.
33. Huybrechts KF, Hernández-Díaz S, Straub L, Gray KJ, Zhu Y, Patorno E, et al. Association of Maternal First-Trimester Ondansetron Use With Cardiac Malformations and Oral Clefts in Offspring. *Jama.* 2018 Dec 18;320(23):2429-37.
34. Huybrechts KF, Bröms G, Christensen LB, Einarsdóttir K, Engeland A, Furu K, et al. Association Between Methylphenidate and Amphetamine Use in Pregnancy and Risk of Congenital Malformations: A Cohort Study From the International Pregnancy Safety Study Consortium. *JAMA Psychiatry.* 2018;75(2):167-75.
35. Bateman BT, Patorno E, Desai RJ, Seely EW, Mogun H, Dejene SZ, et al. Angiotensin-Converting Enzyme Inhibitors and the Risk of Congenital Malformations. *Obstet Gynecol.* 2017 Jan;129(1):174-84.
36. Huybrechts KF, Hernández-Díaz S, Patorno E, Desai RJ, Mogun H, Dejene SZ, et al. Antipsychotic Use in Pregnancy and the Risk for Congenital Malformations. *JAMA Psychiatry.* 2016;73(9):938-46.
37. Chomistek AK, Phiri K, Doherty MC, Calderbank JF, Chiuve SE, McIlroy BH, et al. Development and Validation of ICD-10-CM-based Algorithms for Date of Last Menstrual Period, Pregnancy Outcomes, and Infant Outcomes. *Drug Saf.* 2023 Jan 19.
38. Meserve J, Luo J, Zhu W, Veeravalli N, Bandoli G, Chambers CD, et al. Paternal Exposure to Immunosuppressive and/or Biologic Agents and Birth Outcomes in Patients With Immune-Mediated Inflammatory Diseases. *Gastroenterology.* 2021 Jul;161(1):107-15.e3.
39. Carman WJ, Accortt NA, Anthony MS, Iles J, Enger C. Pregnancy and infant outcomes including major congenital malformations among women with chronic inflammatory arthritis or psoriasis, with and without etanercept use. *Pharmacoepidemiology and Drug Safety.* 2017 2017/09/01;26(9):1109-18.
40. Wang S, Puggioni G, Wu J, Meador KJ, Caffrey A, Wyss R, et al. Prenatal Exposure to Opioids and Neurodevelopmental Disorders in Children: A Bayesian Mediation Analysis. *Am J Epidemiol.* 2024 Feb 5;193(2):308-22.
41. Phiri K, Hernandez-Diaz S, Dugan KB, Williams PL, Dudley JA, Jules A, et al. First trimester exposure to antiretroviral therapy and risk of birth defects. *Pediatr Infect Dis J.* 2014 Jul;33(7):741-6.