

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

Drug Safety

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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
Vasilakis-Scaramozza, 2013 [1]	UK	GPRD	Live born singleton infants, stillbirths, and therapeutic abortions	Birth through first 12 months of life	≥1 code	Read codes mapped to ICD9	Methods	3.1%
Vasilakis-Scaramozza, 2013 [2]	UK	GPRD	Live born singleton infants, stillbirths, and therapeutic abortions	Birth through first 12 months of life	≥1 code	Read codes mapped to ICD9	Methods	2.4%
Vasilakis-Scaramozza, 2013 [3]	UK	GPRD	Live born singleton infants, stillbirths, and therapeutic abortions	Birth through first 12 months of life	≥1 code	Read codes mapped to ICD9	Methods	2.8%

Charlton, 2011 [4]	UK	GPRD	Live births and pregnancy losses	Birth through first 12 months of life	≥1 code	ICD9	Methods	2.4%
Charlton 2010 [5]*	UK	GPRD	Live births	Not specified	≥1 code	ICD9	Methods	NA
Hsiao 2025 [6]	USA	Kaiser Permanente	Singleton live births	Birth through 3 months of life	≥1 code	ICD-9 and ICD-10	Supplemental Digital Content 2	5.8%
Sy, 2018 [7]*	USA	Kaiser Permanente	Live births, miscarriages, elective abortions	Pregnancy through first 180 days of life	≥1 code	ICD-9	Appendix B	6.3%
Li, 2011 [8]*	USA	Kaiser Permanente	Live births	Not specified	≥1 code	ICD-9 CM	Methods	5.4%
Clements, 2019 [9]	USA	RIDOH Vital Statistics and KIDSNET integrated child health information system	Live births	Not specified	≥1 code	ICD-10	Results Table 4	Not reported
Hjort-Pedersen, 2022 [10]	Denmark	Ultrasound database (Astraia), Patient administrative system (PAS), and medical record in each hospital	Fetuses	Pregnancy only	≥1 code	ICD-10	Methods	Not reported

^aAs reported by authors in publications

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

Abbreviations: DOB: date of birth; MCM: major congenital malformation, GPRD: General Practice Research Database; LMP: last menstrual period NS: not stated, RIDOH: Rhode Island Department of Health's Vital Statistics

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