

Disclaimer

The FDA chose a specific outcome algorithm that met its need for a given medical product-outcome assessment. The use of a specific outcome algorithm in a Sentinel assessment should not be interpreted as an endorsement from FDA to use the algorithm for all safety assessments. Investigators should always consider the objective, study design, analytic approach, and data source of a given medical product safety assessment when choosing the outcome algorithm. The suitability of an outcome algorithm may change when applied to different scenarios. For additional information, please refer to the

[Best Practices for Conducting and Reporting Pharmacoepidemiologic Safety Studies Using Electronic Healthcare Data](#) guidance document provided by the FDA.

Overview

Title	Oral Clefts Defined in "A New Propensity Score Matched Analysis Tool for Pregnancy: Replicating A Study of Oral Clefts following Topiramate Use during the First Trimester of Pregnancy"
Request ID	cder_mpl2r_wp015
Description	<p>This report lists International Classification of Diseases, Ninth Revision, Clinical Modification (ICD-9-CM) and Current Procedural Terminology, 4th Edition (CPT-4) diagnosis and procedure codes and algorithms used to define oral clefts among infants in this request.</p> <p>For additional information about the algorithm and how it was defined relative to the cohort and exposures of interest in the inferential analysis, see the analysis page here: https://www.sentinelinitiative.org/methods-data-tools/methods/new-propensity-score-matched-analysis-tool-pregnancy-replicating-study</p>
Outcome	Oral clefts
Algorithm to Define Outcome	Oral cleft outcomes were defined by presence of two diagnosis codes on different dates or one diagnosis code and one procedure/surgery code. Qualifying codes had to be within 90 days of each other and the first of the two codes had to appear in the mother's or the infant's record between delivery and 90 days after delivery.
Query Period	January 1, 2000 - September 30, 2015
Request Send Date	June 19, 2020

Glossary

Care Setting - type of medical encounter or facility where the exposure, event, or condition code was recorded. Possible care settings include: Inpatient Hospital Stay (IP), Non-Acute Institutional Stay (IS), Emergency Department (ED), Ambulatory Visit (AV), and Other Ambulatory Visit (OA). For laboratory results, possible care settings include: Emergency department (E), Home (H), Inpatient (I), Outpatient (O), or Unknown or missing (U)

Outcome - outcome of interest (either primary or secondary)

Principal Diagnosis (PDX) - diagnosis or condition established to be chiefly responsible for admission of the patient to the hospital. 'P' = principal diagnosis, 'S' = secondary diagnosis, 'X' = unspecified diagnosis, '.' = blank. Along with the Care Setting values, forms the Caresetting/PDX parameter.

Query Period - period in which the modular program looks for exposures and outcomes of interest

Request Send Date - date the request was sent to Sentinel Data Partners

List of International Classification of Diseases, Ninth Revision, Clinical Modification (ICD-9-CM) and Current Procedural Terminology, 4th Edition (CPT-4) Diagnosis and Procedure Codes Used to Define Oral Clefts in this Request

Code	Description	Code Type	Code Category
Oral Clefts			
749	Cleft palate and cleft lip	ICD-9-CM	Diagnosis
749.0	Cleft palate	ICD-9-CM	Diagnosis
749.00	Unspecified cleft palate	ICD-9-CM	Diagnosis
749.01	Unilateral cleft palate, complete	ICD-9-CM	Diagnosis
749.02	Unilateral cleft palate, incomplete	ICD-9-CM	Diagnosis
749.03	Bilateral cleft palate, complete	ICD-9-CM	Diagnosis
749.04	Bilateral cleft palate, incomplete	ICD-9-CM	Diagnosis
749.1	Cleft lip	ICD-9-CM	Diagnosis
749.10	Unspecified cleft lip	ICD-9-CM	Diagnosis
749.11	Unilateral cleft lip, complete	ICD-9-CM	Diagnosis
749.12	Unilateral cleft lip, incomplete	ICD-9-CM	Diagnosis
749.13	Bilateral cleft lip, complete	ICD-9-CM	Diagnosis
749.14	Bilateral cleft lip, incomplete	ICD-9-CM	Diagnosis
749.2	Cleft palate with cleft lip	ICD-9-CM	Diagnosis
749.20	Unspecified cleft palate with cleft lip	ICD-9-CM	Diagnosis
749.21	Unilateral cleft palate with cleft lip, complete	ICD-9-CM	Diagnosis
749.22	Unilateral cleft palate with cleft lip, incomplete	ICD-9-CM	Diagnosis
749.23	Bilateral cleft palate with cleft lip, complete	ICD-9-CM	Diagnosis
749.24	Bilateral cleft palate with cleft lip, incomplete	ICD-9-CM	Diagnosis
749.25	Other combinations of cleft palate with cleft lip	ICD-9-CM	Diagnosis
27.62	Correction of cleft palate	ICD-9-CM	Procedure
27.54	Repair of cleft lip	ICD-9-CM	Procedure
27.63	Revision of cleft palate repair	ICD-9-CM	Procedure
00172	Anesthesia for intraoral procedures, including biopsy; repair of cleft palate	CPT-4	Procedure
00102	Anesthesia for procedures involving plastic repair of cleft lip	CPT-4	Procedure
42225	Palatoplasty for cleft palate; attachment pharyngeal flap	CPT-4	Procedure
42200	Palatoplasty for cleft palate, soft and/or hard palate only	CPT-4	Procedure
42210	Palatoplasty for cleft palate, with closure of alveolar ridge; with bone graft to alveolar ridge (includes obtaining graft)	CPT-4	Procedure
42215	Palatoplasty for cleft palate; major revision	CPT-4	Procedure
42220	Palatoplasty for cleft palate; secondary lengthening procedure	CPT-4	Procedure
42205	Palatoplasty for cleft palate, with closure of alveolar ridge; soft tissue only	CPT-4	Procedure
42226	Lengthening of palate, and pharyngeal flap	CPT-4	Procedure
42227	Lengthening of palate, with island flap	CPT-4	Procedure
42235	Repair of anterior palate, including vomer flap	CPT-4	Procedure
42260	Repair of nasolabial fistula	CPT-4	Procedure
40740	Plastic Repair Of Cleft Lip	CPT-4	Procedure
40702	Plastic repair of cleft lip/nasal deformity; primary bilateral, 1 of 2 stages	CPT-4	Procedure
40701	Plastic repair of cleft lip/nasal deformity; primary bilateral, 1-stage procedure	CPT-4	Procedure
40700	Plastic repair of cleft lip/nasal deformity; primary, partial or complete, unilateral	CPT-4	Procedure

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Code	Description	Code Type	Code Category
40720	Plastic repair of cleft lip/nasal deformity; secondary, by recreation of defect and reclosure	CPT-4	Procedure
40761	Plastic repair of cleft lip/nasal deformity; with cross lip pedicle flap (Abbe-Estlander type), including sectioning and inserting of pedicle	CPT-4	Procedure
40799	Unlisted procedure, lips	CPT-4	Procedure