

Title: Development and Validation of ICD-10-CM-based Algorithms for Date of Last Menstrual Period, Pregnancy Outcomes, and Infant Outcomes

Running Title: Validation of ICD-10-CM Algorithms for LMP and Pregnancy Outcomes

Full Names of Authors and Institutional Affiliations:

Andrea K. Chomistek, ScD – Corresponding Author (ORCID: 0000-0002-8764-1446)

Kelesitse Phiri, MS, ScD – Optum, Boston MA (formerly)

Michael C. Doherty, MS – Optum, Boston, MA

Jenna F. Calderbank, MS – Optum, Boston, MA

Stephanie E. Chiuve, ScD – AbbVie, Inc, North Chicago, IL (ORCID: 0000-0002-3524-8917)

Brenda Hinman McIlroy, MD, MPH – AbbVie

Michael C. Snabes, MD, PhD - AbbVie

Cheryl Enger, PhD – Optum, Boston, MA

John D. Seeger, PharmD, DrPH – Optum, Boston, MA (ORCID: 0000-0002-8020-3144)

Optum

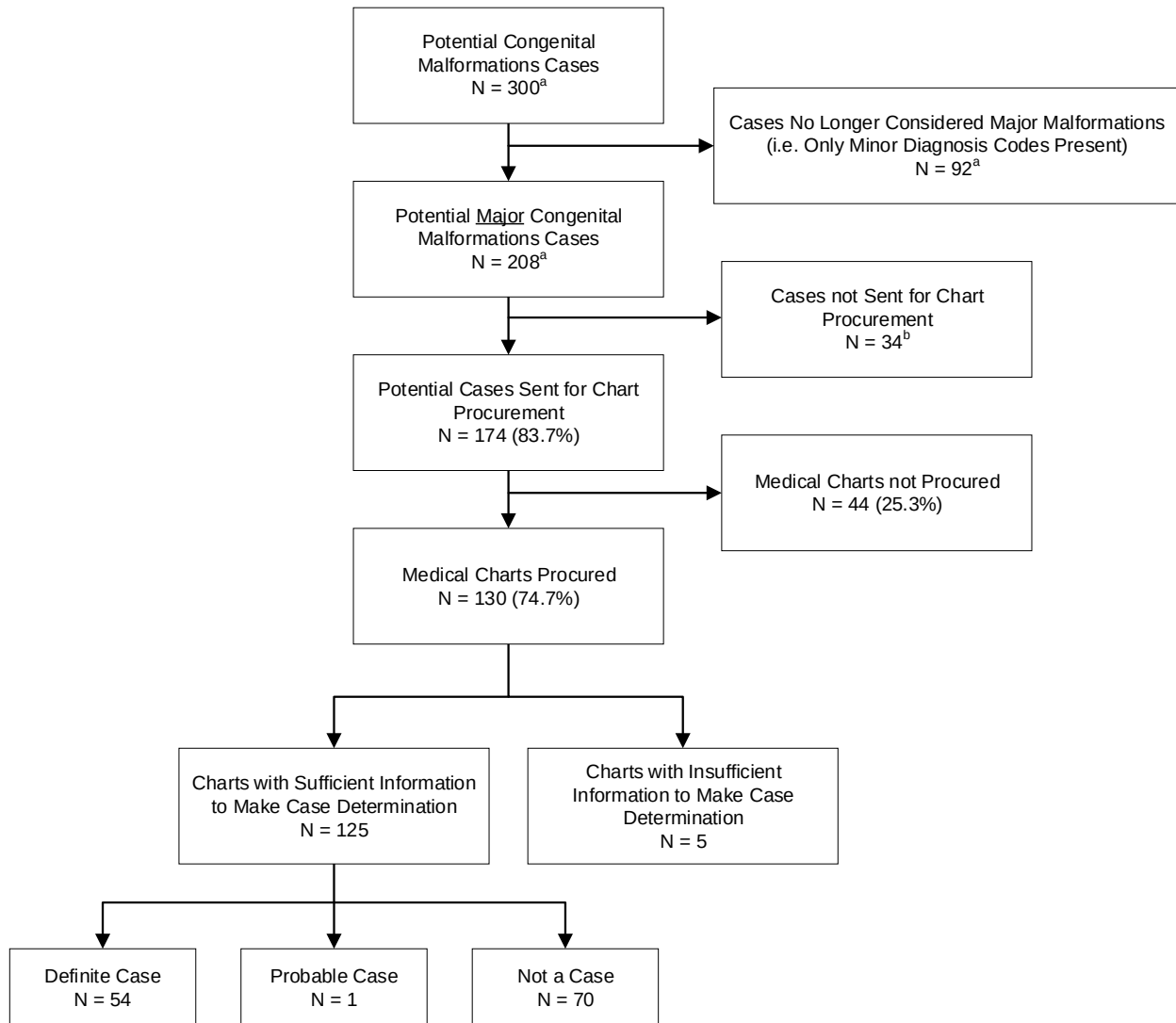
1325 Boylston Street, 11th Floor

Boston, MA 02215

Email: andrea.chomistek@optum.com

SUPPLEMENTAL MATERIAL

Supplemental Figure 1. Identification, Chart Procurement and Validation/Adjudication of Major Congenital Malformations



^a Major congenital malformations were identified in 2 steps. In the first step, 300 cases were identified using the Metropolitan Atlanta Congenital Defects Program (MACDP) reference. In the second step, additional references from the European Surveillance of Congenital Anomalies (EUROCAT) [7] and New York State Department of Health Congenital Malformations were used, resulting in 208 potential cases with major congenital malformations considered for chart procurement.

^b Some cases identified by Optum could not be sent for chart procurement because the providers for the patients have asked to not be contacted.

Supplemental Table 1. Detailed List of International Classification of Diseases, 10th Revision, Clinical Modification (ICD-10-CM) Diagnosis and CPT® Codes to Estimate LMP Date and Identify Pregnancy and Infant Outcomes

LMP Date			
Code	Code Description		Code Type
Z3A.00	Weeks of gestation of pregnancy not specified		ICD-10-CM
Z3A.01	Less than 8 weeks gestation of pregnancy		ICD-10-CM
Z3A.08	8 weeks gestation of pregnancy		ICD-10-CM
Z3A.09	9 weeks gestation of pregnancy		ICD-10-CM
...	...		
Z3A.40	40 weeks gestation of pregnancy		ICD-10-CM
Z3A.41	41 weeks gestation of pregnancy		ICD-10-CM
Z3A.42	42 weeks gestation of pregnancy		ICD-10-CM
Pregnancy Outcomes			
Outcome	Code	Code Description	Code Type
Spontaneous abortion	O02.1	Missed abortion	ICD-10-CM
	O03.**	Spontaneous abortion	ICD-10-CM
	O03.0	Genital tract and pelvic infection following incomplete spontaneous abortion	ICD-10-CM
	O03.1	Delayed or excessive hemorrhaging following incomplete spontaneous abortion	ICD-10-CM
	O03.2	Embolism following incomplete spontaneous abortion	ICD-10-CM
	O03.3*	Other and unspecified complications following incomplete spontaneous abortion	ICD-10-CM
	O03.4	Incomplete spontaneous abortion without complication	ICD-10-CM
	O03.5	Genital tract and pelvic infection following complete or unspecified spontaneous abortion	ICD-10-CM
	O03.6	Delayed or excess hemorrhaging following complete or unspecified spontaneous abortion	ICD-10-CM
	O03.7	Embolism following complete or unspecified spontaneous abortion	ICD-10-CM
	O03.8*	Unspecified complications following complete or unspecified spontaneous abortion	ICD-10-CM
	O03.9	Complete or unspecified spontaneous abortion without complication	ICD-10-CM
	01965	Anesthesia for incomplete or missed abortion procedures	CPT® codes
	59800 - 59811	Treatment of Spontaneous Abortion	CPT® codes
	Placenta previa	O44.**	Placenta previa
O44.0*		Complete placenta previa NOS or without hemorrhage	ICD-10-CM
O44.1*		Complete placenta previa with hemorrhage	ICD-10-CM
O44.2*		Partial placenta previa without hemorrhage	ICD-10-CM
O44.3*		Partial placenta previa with hemorrhage	ICD-10-CM
O44.4*		Low lying placenta NOS or without hemorrhage	ICD-10-CM
O44.5*		Low lying placenta with hemorrhage	ICD-10-CM

Pre-eclampsia	O14.**	Pre-eclampsia	ICD-10-CM
	O14.0*	Mild to moderate pre-eclampsia	ICD-10-CM
	O14.1*	Severe pre-eclampsia	ICD-10-CM
	O14.2*	HELLP syndrome	ICD-10-CM
	O14.9*	Unspecified pre-eclampsia	ICD-10-CM
	O11.*	Pre-existing hypertension with pre-eclampsia	ICD-10-CM
	O11.1	Pre-existing hypertension with pre-eclampsia, first trimester	ICD-10-CM
	O11.2	Pre-existing hypertension with pre-eclampsia, second trimester	ICD-10-CM
	O11.3	Pre-existing hypertension with pre-eclampsia, third trimester	ICD-10-CM
	O11.4	Pre-existing hypertension with pre-eclampsia, complicating childbirth	ICD-10-CM
	O11.5	Pre-existing hypertension with pre-eclampsia, complicating the puerperium	ICD-10-CM
	O11.9	Pre-existing hypertension with pre-eclampsia, unspecified trimester	ICD-10-CM
Premature delivery	O60.10**	Preterm labor with preterm delivery	ICD-10-CM
	O60.12**	Preterm labor second trimester with preterm delivery second trimester	ICD-10-CM
	O60.13**	Preterm labor second trimester with preterm delivery third trimester	ICD-10-CM
	O60.14**	Preterm labor third trimester with preterm delivery third trimester	ICD-10-CM
	P07.2*	Extreme immaturity of newborn	ICD-10-CM
	P07.3*	Preterm (premature) newborn (other)	ICD-10-CM
Infant Outcomes			
Outcome	Code	Code Description	Code Type
Major congenital malformations ^b	Q00-Q07	Congenital malformations of the nervous system	ICD-10-CM
	Q00	Anencephaly and similar malformations	ICD-10-CM
	Q01	Encephalocele	ICD-10-CM
	Q02	Microcephaly	ICD-10-CM
	Q03	Congenital hydrocephalus	ICD-10-CM
	Q04	Other congenital malformations of brain	ICD-10-CM
	Q05	Spina bifida	ICD-10-CM
	Q06	Other congenital malformations of spinal cord	ICD-10-CM
	Q07	Other congenital malformations of nervous system	ICD-10-CM
	Q10-Q18	Congenital malformations of eye, ear, face and neck	ICD-10-CM
	Q10	Congenital malformations of eyelid, lacrimal apparatus	ICD-10-CM
	Q11	Anophthalmos, microphthalmos and macrophthalmos	ICD-10-CM
	Q12	Congenital lens malformations	ICD-10-CM
	Q13	Congenital malformations of anterior segment of eye	ICD-10-CM
	Q14	Congenital malformations of posterior segment of eye	ICD-10-CM
	Q15	Other congenital malformations of eye	ICD-10-CM
	Q16	Congenital malformations of ear causing impairment of	ICD-10-CM

Major congenital malformations ^b	Q17	Other congenital malformations of ear	ICD-10-CM
	Q18	Other congenital malformations of face and neck	ICD-10-CM
	Q20-Q28	Congenital malformations of the circulatory system	ICD-10-CM
	Q20	Congenital malformations of cardiac chambers and	ICD-10-CM
	Q21	Congenital malformations of cardiac septa	ICD-10-CM
	Q22	Congenital malformations of pulmonary and tricuspid valves	ICD-10-CM
	Q23	Congenital malformations of aortic and mitral valves	ICD-10-CM
	Q24	Other congenital malformations of heart	ICD-10-CM
	Q25	Congenital malformations of great arteries	ICD-10-CM
	Q26	Congenital malformations of great veins	ICD-10-CM
	Q27	Other congenital malformations of peripheral vascular system	ICD-10-CM
	Q28	Other congenital malformations of circulatory system	ICD-10-CM
	Q30-Q34	Congenital malformations of the respiratory system	ICD-10-CM
	Q30	Congenital malformations of nose	ICD-10-CM
	Q31	Congenital malformations of larynx	ICD-10-CM
	Q32	Congenital malformations of trachea and bronchus	ICD-10-CM
	Q33	Congenital malformations of lung	ICD-10-CM
	Q34	Other congenital malformations of respiratory system	ICD-10-CM
	Q35-Q37	Cleft lip and cleft palate	ICD-10-CM
	Q35	Cleft palate	ICD-10-CM
	Q36	Cleft lip	ICD-10-CM
	Q37	Cleft palate with cleft lip	ICD-10-CM
	Q38-Q45	Other congenital malformations of the digestive system	ICD-10-CM
	Q38	Other congenital malformations of tongue, mouth and pharynx	ICD-10-CM
	Q39	Congenital malformations of esophagus	ICD-10-CM
	Q40	Other congenital malformations of upper alimentary tract	ICD-10-CM
	Q41	Congenital absence, atresia and stenosis of small intestine	ICD-10-CM
	Q42	Congenital absence, atresia and stenosis of large intestine	ICD-10-CM
	Q43	Other congenital malformations of intestine	ICD-10-CM
	Q44	Congenital malformations of gallbladder, bile ducts and liver	ICD-10-CM
	Q45	Other congenital malformations of digestive system	ICD-10-CM
	Q50-Q56	Congenital malformations of genital organs	ICD-10-CM
	Q50	Congenital malformations of ovaries, fallopian tubes and broad ligaments	ICD-10-CM
	Q51	Congenital malformations of uterus and cervix	ICD-10-CM
	Q52	Other congenital malformations of female genitalia	ICD-10-CM
	Q53	Undescended and ectopic testicle	ICD-10-CM
	Q54	Hypospadias	ICD-10-CM
	Q55	Other congenital malformations of male genital organs	ICD-10-CM
	Q56	Indeterminate sex and pseudohermaphroditism	ICD-10-CM

Major congenital malformations ^b	Q60-Q64	Congenital malformations of the urinary system	ICD-10-CM
	Q60	Renal agenesis and other reduction defects of kidney	ICD-10-CM
	Q61	Cystic kidney disease	ICD-10-CM
	Q62	Congenital obstructive defects of renal pelvis and congenital malformations of ureter	ICD-10-CM
	Q63	Other congenital malformations of kidney	ICD-10-CM
	Q64	Other congenital malformations of urinary system	ICD-10-CM
	Q65-Q79	Congenital malformations and deformations of the musculoskeletal system	ICD-10-CM
	Q65	Congenital deformities of hip	ICD-10-CM
	Q66	Congenital deformities of feet	ICD-10-CM
	Q67	Congenital musculoskeletal deformities of head, face, spine and chest	ICD-10-CM
	Q68	Other congenital musculoskeletal deformities	ICD-10-CM
	Q69	Polydactyly	ICD-10-CM
	Q70	Syndactyly	ICD-10-CM
	Q71	Reduction defects of upper limb	ICD-10-CM
	Q72	Reduction defects of lower limb	ICD-10-CM
	Q73	Reduction defects of unspecified limb	ICD-10-CM
	Q74	Other congenital malformations of limb(s)	ICD-10-CM
	Q75	Other congenital malformations of skull and face bones	ICD-10-CM
	Q76	Congenital malformations of spine and bony thorax	ICD-10-CM
	Q77	Osteochondrodysplasia with defects of growth of tubular bones and spine	ICD-10-CM
	Q78	Other osteochondrodysplasias	ICD-10-CM
	Q79	Congenital malformations of musculoskeletal system, not elsewhere classified	ICD-10-CM
	Q80-Q89	Other congenital malformations	ICD-10-CM
	Q80	Congenital ichthyosis	ICD-10-CM
	Q81	Epidermolysis bullosa	ICD-10-CM
	Q82	Other congenital malformations of skin	ICD-10-CM
	Q83	Congenital malformations of breast	ICD-10-CM
	Q84	Other congenital malformations of integument	ICD-10-CM
	Q85	Phakomatoses, not elsewhere classified	ICD-10-CM
	Q86	Congenital malformation syndromes due to known exogenous causes, not elsewhere classified	ICD-10-CM
	Q87	Other specified congenital malformation syndromes affecting multiple systems	ICD-10-CM
	Q89	Other congenital malformations, not elsewhere classified	ICD-10-CM
Low birthweight	P07.0*	Extremely low birth weight newborn	ICD-10-CM
	P07.1*	Other low birth weight newborn	ICD-10-CM

Small for gestational age	P05.**	Disorders of newborn related to slow fetal growth and fetal malnutrition	ICD-10-CM
	P05.0*	Newborn light for gestational age	ICD-10-CM
	P05.1*	Newborn small for gestational age	ICD-10-CM
	P05.2	Newborn affected by fetal (intrauterine) malnutrition not light or small for gestational age	ICD-10-CM
	P05.9	Newborn affected by slow intrauterine growth, unspecified	ICD-10-CM

^aCPT © Copyright 2021 American Medical Association. All rights reserved.

^b The Metropolitan Atlanta Congenital Defects Program (MACDP) ²², European Surveillance of Congenital Anomalies (EUROCAT) ²³ and New York State Department of Health Congenital Malformations Registry ²⁴ references were used to create a list of minor anomalies to exclude from the code category Q00 – Q89 in order to identify major congenital malformations.

Supplemental Table 2. Baseline Characteristics of Pregnant Women in Optum DAPI, 01 January 2016 - 31 December 2017

	Source Population N = 53,956	
	N	%
Demographics		
Age at LMP (years)		
Median, (p25, p75)	31 (28, 35)	
18 - 24	6,485	12.0
25 - 34	32,458	60.2
34 - 44	14,614	27.1
≥ 45	399	0.7
Race/Ethnicity ^a		
White	27,865	51.6
Black/African American	3,922	7.3
Hispanic	5,608	10.4
Asian	2,221	4.1
Unknown	14,340	26.6
Geographic region		
Northeast	5,193	9.6
Midwest	13,815	25.6
South	24,575	45.6
West	10,255	19.0
Unknown	118	0.2
Calendar year of LMP		
2016	37,305	69.1
2017	16,651	30.9
Comorbidities^c		
Abnormal vaginal bleeding	2,434	4.5
Diabetes mellitus	1,705	3.2
Hypertension	1,646	3.1
Gestational diabetes (during pregnancy)	4,309	8.0
Pre-existing hypertension	1,719	3.2
Gestational hypertension\pre-eclampsia\ eclampsia (during pregnancy)	5,404	10.0
Obesity	3,595	6.7
Current or history of Rhesus D complication		
12 months prior to pregnancy	314	0.6
During pregnancy	2,844	5.3
Any anemia, thrombophilia (other blood disorder)		
12 months prior to pregnancy	2128	3.9
During pregnancy	6780	12.6

Supplemental Table 2. Baseline Characteristics of Pregnant Women in Optum DAPI, 01 January 2016 - 31 December 2017 Continued

	Source Population N = 53,956	
	N	%
Migraine	4,446	8.2
Depression	3,426	6.4
Anxiety disorders	5,171	9.6
Thyroid disease ^d	4,101	7.6
Any cardiovascular disease (other than hypertension)	122	0.2
Any kidney disease	86	0.2
Any history of cancer (including leukemia, cervical)	7,669	14.2
Pregnancy history (prior elective abortions/miscarriages)	8,478	15.7
Exposure to teratogens		
6 months prior to pregnancy	1,161	2.2
During pregnancy	2,441	4.5
Lifestyle choices		
Smoking or tobacco use		
6 months prior to pregnancy	1,245	2.3
During pregnancy	1,801	3.3
Alcohol or substance abuse		
6 months prior to pregnancy	221	0.4
During pregnancy	487	0.9
Use of any birth control	12,792	23.7
Healthcare Utilization^b		
	Median	p25, p75
Number of 3-digit diagnosis codes	4	1 , 9
Number of dispensings of prenatal vitamins		
6 months prior to pregnancy	1	0 , 3
During pregnancy	1	0 , 3
Number of dispensings of folic acid		
6 months prior to pregnancy	1	0 , 3
During pregnancy	1	0 , 3
Number of obstetric procedures ^e	8	4, 13
Number of Assisted reproductive technology procedures and treatments ^c	8	4, 13
Number of drugs dispensed	1	0 , 3
Number of pre-natal visits	4	1, 8
Number of other outpatient physician visits	2	1 , 4
Number of hospitalizations	0	0 , 0
Length of stay of hospitalizations	0	0 , 0
Number of emergency department visits	0	0 , 0

Abbreviations : LMP, last menstrual period

Note: Only ICD-10-CM codes were used to identify baseline characteristics and therefore pregnancies that started earlier in 2016 would have some of the baseline period occurring during ICD-9-CM coding time period; hence, the comorbidities and other characteristics for these women may be underestimated.

a Race is defined at the woman-level, instead of the pregnancy-episode level

b Past 6 months

c Past 12 months

d Includes Graves' disease, hyper-or hypo-thyroid etc.

e Includes amniocentesis, chorionic villus sampling, fetal monitoring, ultrasonography, alpha-fetoprotein test, ART procedures and treatments

Supplemental Table 3. Baseline Characteristics for the Subset of Women Included in the Validation Sample, Stratified by Chart Adjudication Status

	Women Whose Charts Could Be Adjudicated N = 365		Women Whose Charts Could Not Be Adjudicated N = 293	
	N	%	N	%
Demographics				
Age at LMP (years)				
Median, (p25, p75)	32	29 , 35	32	28 , 35
18-24	25	6.8	23	7.8
25-34	224	61.4	184	62.8
≥ 35	116	31.8	86	29.4
Race/Ethnicity ^a				
White	207	56.7	136	46.4
Black/African American	23	6.3	16	5.5
Hispanic	35	9.6	32	10.9
Asian	16	4.4	18	6.1
Unknown	84	23.0	91	31.1
Geographic region				
Northeast	38	10.4	34	11.6
Midwest	92	25.2	56	19.1
South	166	45.5	145	49.5
West	69	18.9	57	19.5
Unknown	0	0.0	1	0.3
	Median	p25, p75	Median	p25, p75
Healthcare Utilization				
Number of 3-digit diagnosis codes	5	2 , 9	4	1 , 9
Number of obstetric procedures ^b	10	6 , 17	11	5 , 19
Number of drugs dispensed	2	0 , 4	1	0 , 4
Number of pre-natal visits	5	2 , 10	5	2 , 11
Number of other outpatient physician visits	2	1 , 4	2	1 , 4
Gestational Age, weeks	34	10 , 38	35	10 , 38
	N	%	N	%
Outcomes				
Placenta previa	23	6.3	27	9.2
Pre-eclampsia	23	6.3	27	9.2
Early pregnancy loss	118	32.3	82	28
Premature delivery	26	7.1	24	8.2
Low birthweight	27	7.4	23	7.8
Small for gestational age	23	6.3	27	9.2
Major congenital malformations	125	34.2	83	28.3

Abbreviations : LMP, last menstrual period

a Race is defined at the woman-level, instead of the pregnancy-episode level

b Includes amniocentesis, chorionic villus sampling, fetal monitoring, ultrasonography, alpha-fetoprotein test, ART procedures and treatments

Supplemental Table 4a. Number of Days Between Estimated Date of LMP Based on Earliest Z3A Code in DAPI and Adjudicated LMP, Overall and According to Pregnancy Outcome

	Overall (n = 157)		Spontaneous Abortion (n = 73)		Premature Delivery (n = 29)		Placenta Previa (n = 23)		Pre-eclampsia (n = 32)	
	Median	IQR	Median	IQR	Median	IQR	Median	IQR	Median	IQR
Difference in days*	4.0	2.0-9.0	7.0	3.0-17.0	3.0	1.5-5.5	3.0	1.0-5.0	5.0	1.0-6.0
Stratified by Age at LMP (years)										
18 - 24	5.5	1.8-8.0	7.0	1.0-14.0	6.0	2.8-20.5	3.0	1.0-5.5	6.0	6.0-6.0
25 - 34	4.0	2.0-8.0	7.0	3.0-22.5	2.0	1.0-4.0	3.0	2.0-5.0	5.0	2.0-7.0
35 - 44	4.5	2.0-12.0	10.0	3.0-19.0	5.0	1.0-6.0	1.0	0.5-2.0	4.0	1.0-6.0
≥ 45	0.0	0.0-0.0	N/A	N/A	N/A	N/A	0.0	0.0-0.0	N/A	N/A
	N	%	N	%	N	%	N	%	N	%
Days between estimated and adjudicated LMP										
-29 or more days	4	2.6	3	4.1	1	3.5	0	0.0	0	0.0
-15 to -28	1	0.6	0	0.0	0	0.0	0	0.0	1	3.1
-8 to -14	3	1.9	1	1.4	1	3.5	0	0.0	1	3.1
-4 to -7	5	3.2	2	2.7	1	3.5	0	0.0	2	6.3
-1 to -3	7	4.5	3	4.1	0	0.0	2	8.7	2	6.3
0	15	9.6	6	8.2	3	10.3	4	17.4	2	6.3
+1 to +3	40	25.5	9	12.3	14	48.3	9	39.1	8	25.0
+4 to +7	34	21.7	11	15.1	5	17.2	7	30.4	11	34.4
+8 to +14	18	11.5	11	15.1	3	10.3	1	4.4	3	9.4
+15 to +28	7	4.5	7	9.6	0	0.0	0	0.0	0	0.0
+29 or more days	9	5.7	8	11.0	0	0.0	0	0.0	1	3.1
Insufficient information on LMP in chart	14	8.9	12	16.4	1	3.5	0	0.0	1	3.1

Abbreviations: DAPI, Dynamic Assessment of Pregnancies and Infants; IQR, interquartile range; LMP, last menstrual period; N/A, not applicable

*Based on absolute value of the number of days between estimated LMP and adjudicated LMP

Supplemental Table 4b. Number of Days Between Estimated Date of LMP Among Pregnancies Without Z3A Codes and Adjudicated LMP, Overall and According to Pregnancy Outcome

	Overall (n = 48)		Spontaneous Abortion (n = 46)		Premature Delivery (n = 1)		Placenta Previa (n = 0)		Pre-eclampsia (n = 1)	
	Median	IQR	Median	IQR	Median	IQR	Median	IQR	Median	IQR
Difference in days* Stratified by Age at LMP (years)	16.0	8.0-25.0	15.0	8.0-23.0	27.0	27.0-27.0	N/A	N/A	27.0	27.0-27.0
18 - 24	19.5	11.0-41.5	19.5	11.0-41.5	N/A	N/A	N/A	N/A	N/A	N/A
25 - 34	18.0	8.5-29.0	17.5	8.0-31.0	27.0	27.0-27.0	N/A	N/A	27.0	27.0-27.0
35 - 44	10.0	7.0-23.0	10.0	7.0-23.0	N/A	N/A	N/A	N/A	N/A	N/A
≥ 45	N/A	N/A	N/A	N/A	N/A	N/A	N/A	N/A	N/A	N/A
	N	%	N	%	N	%	N	%	N	%
Days between estimated and adjudicated LMP										
-29 or more days	4	8.3	4	8.7	0	0.0	0	0.0	0	0.0
-15 to -28	12	25.0	10	21.7	1	100.0	0	0.0	1	100.0
-8 to -14	3	6.3	3	6.5	0	0.0	0	0.0	0	0.0
-4 to -7	4	8.3	4	8.7	0	0.0	0	0.0	0	0.0
-1 to -3	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0
0	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0
+1 to +3	1	2.1	1	2.2	0	0.0	0	0.0	0	0.0
+4 to +7	3	6.3	3	6.5	0	0.0	0	0.0	0	0.0
+8 to +14	5	10.4	5	10.9	0	0.0	0	0.0	0	0.0
+15 to +28	1	2.1	1	2.2	0	0.0	0	0.0	0	0.0
+29 or more days	2	4.2	2	4.4	0	0.0	0	0.0	0	0.0
Insufficient information on LMP in chart	13	27.1	13	28.3	0	0.0	0	0.0	0	0.0

Abbreviations: DAPI, Dynamic Assessment of Pregnancies and Infants; IQR, interquartile range; LMP, last menstrual period; N/A, not applicable.

*Based on absolute value of the number of days between estimated LMP and adjudicated LMP

Supplemental Table 5a. Positive Predictive Values for Candidate Claims-based Algorithms: Placenta Previa

Outcome Algorithms	Algorithm-defined Outcomes ^a	Records Procured and Adjudicated	Adjudicators' Determination								PPV (%) ^b	95% CI
			Definite Cases		Probable Cases		Non-cases		Insufficient Information			
			N	%	N	%	N	%	N	%		
Algorithm 1 (at least 1 claim)	47	26	2	7.7	1	3.8	20	76.9	3	11.5	13.0	0.0 - 26.8
Algorithm 2 (at least 2 claims on separate days)	38	24	2	8.3	1	4.2	18	75.0	3	12.5	14.3	0.0 - 29.3
Algorithm 3a (2 claims separated by at least 7 days)	37	23	2	8.7	1	4.3	17	73.9	3	13.0	15.0	0.0 - 30.6
Algorithm 3b (2 claims separated by at least 28 days)	31	18	1	5.6	0	0.0	15	83.3	2	11.1	6.3	0.0 - 18.1
Algorithm 4 (at least 1 claim from the hospital or OB/GYN)	46	25	2	8.0	1	4.0	19	76.0	3	12.0	13.6	0.0 - 28.0
Algorithm 4a (at least 1 claim from the hospital)	22	14	1	7.1	1	7.1	9	64.3	3	21.4	18.2	0.0 - 41.0
Algorithm 4b (at least 1 claim from the OB/GYN)	42	24	2	8.3	1	4.2	18	75.0	3	12.5	14.3	0.0 - 29.3
Algorithm 5 (at least 1 claim from inpatient stay or other)	47	26	2	7.7	1	3.8	20	76.9	3	11.5	13.0	0.0 - 26.8
Algorithm 5a (at least 1 claim from inpatient stay)	15	8	1	12.5	1	12.5	5	62.5	1	12.5	28.6	0.0 - 62.0
Algorithm 5b (at least 1 claim from professional visit)	39	21	2	9.5	1	4.8	15	71.4	3	14.3	16.7	0.0 - 33.9
Algorithm 6 (at least 1 claim +/- 14 days from the delivery date)	15	9	1	11.1	1	11.1	6	66.7	1	11.1	25.0	0.0 - 55.0
Algorithm 6a (at least 1 claim +14 days from the delivery date)	15	9	1	11.1	1	11.1	6	66.7	1	11.1	25.0	0.0 - 55.0
Algorithm 6b (at least 1 claim - 14 days from the delivery date)	5	4	0	0.0	1	25.0	2	50.0	1	25.0	33.3	0.0 - 86.7

Abbreviations: CI, confidence interval; OB/GYN, obstetrics and gynecology; PPV, positive predictive value

^a From the validation sample of randomly selected outcomes

^b Charts with insufficient information for each algorithm were excluded from the denominator of the PPV; the numerator included definite and probable cases.

Supplemental Table 5b. Positive Predictive Values for Candidate Claims-based Algorithms: Pre-eclampsia

Outcome Algorithms	Algorithm-defined Outcomes ^a	Records Procured and Adjudicated	Adjudicators' Determination								PPV (%) ^b	95% CI
			Definite Cases		Probable Cases		Non-cases		Insufficient Information			
			N	%	N	%	N	%	N	%		
Algorithm 1 (at least 1 claim)	48	34	14	41.2	4	11.8	5	14.7	11	32.4	78.3	61.4 - 95.1
Algorithm 2 (at least 2 claims on separate days)	32	24	11	45.8	4	16.7	2	8.3	7	29.2	88.2	72.9 - 100.0
Algorithm 3 (2 claims separated by at least 7 days)	10	8	4	50.0	1	12.5	0	0.0	3	37.5	100.0	100.0 - 100.0
Algorithm 4 (at least 1 claim from the hospital, OB/GYN or pathology)	46	34	14	41.2	4	11.8	5	14.7	11	32.4	78.3	61.4 - 95.1
Algorithm 4a (at least 1 claim from the hospital)	43	31	14	45.2	4	12.9	5	16.1	8	25.8	78.3	61.4 - 95.1
Algorithm 4b (at least 1 claim from OB/GYN)	35	26	12	46.2	4	15.4	2	7.7	8	30.8	88.9	74.4 - 100.0
Algorithm 4c (at least 1 claim from pathology)	18	12	7	58.3	2	16.7	1	8.3	2	16.7	90.0	71.4 - 100.0
Algorithm 5 (at least 1 claim from an inpatient stay)	43	32	14	43.8	4	12.5	3	9.4	11	34.4	85.7	70.7 - 100.0

Abbreviations: CI, confidence interval; OB/GYN, obstetrics and gynecology; PPV, positive predictive value

^a From the validation sample of randomly selected outcomes

^b Charts with insufficient information for each algorithm were excluded from the denominator of the PPV; the numerator included definite and probable cases.

Supplemental Table 5c. Positive Predictive Values for Candidate Claims-based Algorithms: Premature Delivery

Outcome Algorithms	Algorithm-defined Outcomes ^a	Records Procured and Adjudicated	Adjudicators' Determination								PPV (%) ^b	95% CI
			Definite Cases		Probable Cases		Non-cases		Insufficient Information			
			N	%	N	%	N	%	N	%		
Algorithm 1 (at least 1 claim)	44	30	23	76.7	1	3.3	2	6.7	4	13.3	92.3	82.1 - 100.0
Algorithm 2 (at least 2 claims on separate days)	20	13	12	92.3	0	0.0	0	0.0	1	7.7	100.0	100.0 - 100.0
Algorithm 3 (2 claims separated by at least 7 days)	3	2	2	100.0	0	0.0	0	0.0	0	0.0	100.0	100.0 - 100.0
Algorithm 4 (at least 1 claim from the hospital, OB/GYN or pathology)	44	30	23	76.7	1	3.3	2	6.7	4	13.3	92.3	82.1 - 100.0
Algorithm 4a (at least 1 claim from the hospital)	36	23	18	78.3	1	4.3	0	0.0	4	17.4	100.0	100.0 - 100.0
Algorithm 4b (at least 1 claim from OB/GYN)	22	16	12	75.0	1	6.3	2	12.5	1	6.3	86.7	69.5 - 100.0
Algorithm 4c (at least 1 claim from pathology)	16	10	8	80.0	0	0.0	1	10.0	1	10.0	88.9	68.4 - 100.0
Algorithm 5 (at least 1 claim from an inpatient stay)	44	30	23	76.7	1	3.3	2	6.7	4	13.3	92.3	82.1 - 100.0

Abbreviations: CI, confidence interval; OB/GYN, obstetrics and gynecology; PPV, positive predictive value

^a From the validation sample of randomly selected outcomes

^b Charts with insufficient information for each algorithm were excluded from the denominator of the PPV; the numerator included definite and probable cases.

Supplemental Table 6. Counts of Placenta Previa Outcomes by ICD-10 Code (Patient-Level) Based on Code Most Proximal to Pregnancy End Date

		Patients for Whom Medical Records were Sought N = 47		Patients for Whom Medical Records were Adjudicated N = 26		Definite or Probable Cases N = 3	
ICD-10 Code	ICD-10 Code Description	N	%	N	%	N	%
O44.0*	Complete placenta previa NOS or without hemorrhage	19	40.4	9	34.6	0	0.0
O44.1*	Complete placenta previa with hemorrhage	8	17.0	6	23.1	3	100.0
O44.2*	Partial placenta previa NOS or without hemorrhage	3	6.4	1	3.9	0	0.0
O44.3*	Partial placenta previa with hemorrhage	1	2.1	0	0.0	0	0.0
O44.4*	Low lying placenta NOS or without hemorrhage	14	29.8	9	34.6	0	0.0
O44.5*	Low lying placenta with hemorrhage	2	4.3	1	3.9	0	0.0

Abbreviations: N/A, not applicable

Supplemental Table 7. Positive Predictive Values of Claims-based Algorithm^a for Major Congenital Malformations by Body System

Body System	Records Procured and Adjudicated^b	Confirmed by Adjudicator^c	PPV^d (%)	95% CI
Nervous system	14	3	21.4	0.0 - 42.9
Eye, ear, face and neck	4	2	50.0	1.0 - 99.0
Circulatory	39	21	53.8	38.2 - 69.5
Respiratory	2	2	100.0	100.0 - 100.0
Oro-facial clefts	7	7	100.0	100.0 - 100.0
Digestive	6	2	33.3	0.0 - 71.1
Genital	15	6	40.0	15.2 - 64.8
Urinary	25	8	32.0	13.7 - 50.3
Musculoskeletal	22	7	31.8	12.4 - 51.3
Other	12	2	16.7	0.0 - 37.8

Abbreviations: CI, confidence interval; PPV, positive predictive value

^a Claims-identified outcomes are based on the simple algorithm (i.e. at least 1 diagnosis claim for an outcome).

^b Includes records with a claim for a major malformation in each body system for which medical records with sufficient information for adjudication were obtained. Some records included claims for a malformation in more than one system.

^c Includes definite and probable cases of all major malformations from each infant based on organ system classification of malformations by the adjudicators. Only cases who also had a claim for a malformation in the same organ system are included.

^d Charts with insufficient information were excluded from the denominator of the PPV; the numerator included definite and probable cases with a claim for a malformation in the same organ system.

Supplemental Table 8a. Positive Predictive Values for Candidate Claims-based Algorithms: Low Birthweight

Outcome Algorithms	Algorithm-defined Outcomes ^a	Records Procured and Adjudicated	Adjudicators' Determination								PPV (%) ^b	95% CI
			Definite Cases		Probable Cases		Non-cases		Insufficient Information			
			N	%	N	%	N	%	N	%		
Algorithm 1 (at least 1 claim)	48	27	26	96.3	0	0.0	1	3.7	0	0.0	96.3	89.2 - 100.0
Algorithm 2 (at least 2 claims on separate days)	34	20	20	100.0	0	0.0	0	0.0	0	0.0	100.0	100.0 - 100.0
Algorithm 3 (2 claims separated by at least 7 days)	9	4	4	100.0	0	0.0	0	0.0	0	0.0	100.0	100.0 - 100.0
Algorithm 4 (at least 1 claim from the hospital or pediatrician)	47	27	26	96.3	0	0.0	1	3.7	0	0.0	96.3	89.2 - 100.0
Algorithm 4a (at least 1 claim from the hospital)	41	22	22	100.0	0	0.0	0	0.0	0	0.0	100.0	100.0 - 100.0
Algorithm 4b (at least 1 claim from pediatrician)	27	18	17	94.4	0	0.0	1	5.6	0	0.0	94.4	83.9 - 100.0
Algorithm 5 (at least 1 claim from an inpatient stay)	47	26	26	100.0	0	0.0	0	0.0	0	0.0	100.0	100.0 - 100.0

Abbreviations: CI, confidence interval; PPV, positive predictive value

^a From the validation sample of randomly selected outcomes

^b Charts with insufficient information for each algorithm were excluded from the denominator of the PPV; the numerator included definite and probable cases.

Supplemental Table 8b. Positive Predictive Values for Candidate Claims-based Algorithms: Small for Gestational Age

Outcome Algorithms	Algorithm-defined Outcomes ^a	Records Procured and Adjudicated	Adjudicators' Determination								PPV (%) ^b	95% CI
			Definite Cases		Probable Cases		Non-cases		Insufficient Information			
			N	%	N	%	N	%	N	%		
Algorithm 1 (at least 1 claim)	46	26	7	26.9	1	3.8	15	57.7	3	11.5	34.8	15.3 - 54.2
Algorithm 2 (at least 2 claims on separate days)	25	15	6	40.0	1	6.7	8	53.3	0	0.0	46.7	21.4 - 71.9
Algorithm 3 (2 claims separated by at least 7 days)	3	1	0	0.0	1	100.0	0	0.0	0	0.0	100.0	100.0 - 100.0
Algorithm 4 (at least 1 claim from the hospital, OB/GYN or pathology)	44	24	6	25.0	1	4.2	14	58.3	3	12.5	33.3	13.2 - 53.5
Algorithm 4a (at least 1 claim from the hospital)	35	20	5	25.0	1	5.0	11	55.0	3	15.0	35.3	12.6 - 58.0
Algorithm 4b (at least 1 claim from the pediatrician)	14	8	3	37.5	0	0.0	5	62.5	0	0.0	37.5	4.0 - 71.0
Algorithm 5 (at least 1 claim from an inpatient stay)	45	26	7	26.9	1	3.8	15	57.7	3	11.5	34.8	15.3 - 54.2

Abbreviations: CI, confidence interval; OB/GYN, obstetrics and gynecology; PPV, positive predictive value

^a From the validation sample of randomly selected outcomes

^b Charts with insufficient information for each algorithm were excluded from the denominator of the PPV; the numerator included definite and probable cases.

APPENDIX

Instructions for Case Adjudication

To facilitate case review, adjudication guidelines outlined below were provided to the adjudicators. Using the adjudication guidelines in conjunction with his/her clinical knowledge and judgment, the clinician adjudicated the diagnosis and ascertained the level of diagnostic certainty for each case (i.e., definite, probable, non-case, insufficient information to determine). If the case was determined to be definite or probable, the adjudicator also noted the date of the diagnosis as recorded by the treating physician in the medical record.

Case Classifications

1. Definite Case

Patient should be classified as a definite case if the medical records have dated documentation of at least 1 of the following criteria:

a. Placenta Previa Case Status

Physician notes stating that the woman has placenta previa with indication that the previa (covering the internal cervical os) persisted into the second or third trimester, or there was indication of a caesarian section delivery due to bleeding in the medical record, and

Abdominal ultrasound, or transvaginal ultrasound report(s)

b. Pre-eclampsia Case Status

Mild pre-eclampsia:

systolic blood pressure (SBP) ≥ 140 mmHg or diastolic blood pressure (DBP) ≥ 90 mmHg, and either:

proteinuria ≥ 0.3 g/24 h

or

blood tests that show kidney or liver dysfunction

Fluid in the lungs and difficulty breathing

Visual impairments

Severe pre-eclampsia:

SBP > 160 mmHg or DBP > 110 mmHg on two occasions at least 4 hours apart, or

severe proteinuria (≥ 5 g/24 h) or protein-to-creatinine ratio $\geq .3$ mg/dl or

test results suggesting kidney or liver damage, or

severe headache, or unexplained stomach pain that does not respond to medication, or

symptoms that include visual disturbances, difficulty breathing, or fluid buildup or

medication (e.g. Magnesium sulphate) or

early delivery

c. Spontaneous Abortion Case Status

Physician notes stating that a spontaneous abortion, missed abortion, or incomplete abortion occurred before the 20th week of gestation, and

At least one of the following:

Pelvic ultrasound, transvaginal ultrasound or other imaging reports

Autopsy/pathology reports

Reported change in human chorionic gonadotrophin level

Surgical reports (dilation and curettage or evacuation)

Reports of medical expulsion of uterus (use of misoprostol or mifepristone)

d. Premature Delivery Case Status

Livebirth delivery with gestational age at birth between the 20th and 36th completed weeks of gestation.

e. Endometriosis Case Status

Operative or pathology report indicating the woman has endometriosis.

f. Uterine Fibroids Case Status

Physician notes stating that the woman has uterine fibroids and ultrasound evidence.

g. Low Birth Weight Case Status

Birth weight $\leq$ 2,500 grams (5.5 lbs or 5 lbs 8 oz)

h. Small for Gestational Age Case Status

Physician notes stating that the infant is small for gestational age, or

Birth weight and gestational age are available, or

Growth curves are available

i. Congenital Malformation Case Status

Physician/specialist notes stating that the infant has a congenital malformation, and

At least one of the following:

Examination of placenta and umbilical cord

Physical exam including standard measurements reports (weight, length, head circumference) and inclusion of notations made about cranium size and appearance, eyes, ears, nose, mouth and throat, neck, chest, cardiovascular, abdomen, genitourinary, spine, extremities, skin, hair, nails, etc.

Surgical reports

Postnatal imaging (computed topography (CT) scan or magnetic resonance imaging (MRI), echocardiogram, ultrasound or other radiographs) report(s)

2. Probable Case

A patient should be classified as a probable case if the information in the medical record does not meet all of the requirements for the definite case definition criteria, but sufficient clinical information is present for the patient to be classified as a probable case in the adjudicator's best clinical judgement.

3. Non-Case

A patient should be classified as a non-case if the information in the medical record does not indicate any presence of the specific outcome of interest in the adjudicator's best clinical judgement.

4. Insufficient Information

For all outcomes, this category should be chosen if the medical record provided does not contain the specific reports and notes needed in order to make a final adjudication decision.