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Trends in Neonatal Opioid Withdrawal Syndrome and Opioid Exposure Diagnoses Among Infants With Private Health Insurance, 2016-2021: Introduction of the P04.14 ICD-10-CM Code

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Abstract

Objective: The opioid epidemic has led to a surge in diagnoses of neonatal opioid withdrawal syndrome (NOWS). Many states track the incidence of NOWS by using the P96.1 *International Classification of Diseases, Tenth Revision, Clinical Modification* (ICD-10-CM) code for "neonatal withdrawal symptoms from maternal use of drugs of addiction." In October 2018, an ICD-10-CM code for neonatal opioid exposure (P04.14) was introduced. This code can be used when an infant is exposed to opioids in utero but does not have clinically significant withdrawal symptoms. We analyzed the effect of the P04.14 code on the incidence rate of NOWS (P96.1) and "other" neonatal drug exposure diagnoses (P04.49).

Methods: We used private health insurance data collected for infants in the United States from the first quarter of 2016 through the third quarter of 2021 to describe incidence rates for each code over time and examine absolute and percentage changes before and after the introduction of code P04.14.

Results: The exclusive use of code P96.1 declined from an incidence rate per 1000 births of 1.08 in 2016-2018 to 0.70 in 2019-2021, a −35.7% (95% CI, −47.6% to −23.8%) reduction. Use of code P04.49 only declined from an incidence rate of 2.34 in 2016-2018 to 1.64 in 2019-2021, a −30.0% (95% CI, −36.4% to −23.7%) reduction. Use of multiple codes during the course of treatment increased from an average incidence per 1000 births of 0.56 in 2016-2018 to 0.79 in 2019-2021, a 45.5% (95% CI, 24.8%-66.1%) increase.

Conclusion: The introduction of ICD-10-CM code P04.14 altered the use of other neonatal opioid exposure codes. The use of multiple codes increased, indicating that some ambiguity may exist about which ICD-10-CM code is most appropriate for a given set of symptoms.

Keywords

neonatal abstinence syndrome, neonatal opioid withdrawal syndrome, opioid epidemic, eat, sleep, console

The opioid epidemic has led to a surge in the incidence of neonatal opioid withdrawal syndrome (NOWS), a condition also referred to as neonatal abstinence syndrome,[1] which is caused by in utero exposure to opioids.[2] NOWS is associated with increases in hospital spending[3] and lengths of stay,[3] seizures,[4] difficulty feeding,[4] and central nervous system defects.[5] In utero opioid exposure is associated with health risks such as atrioventricular septal defects,[6] spina bifida,[6] and developmental delays.[7] These factors have led many states to track diagnosis codes for NOWS and/or opioid exposure. Some states exclusively track the *International Classification of Diseases, Tenth Revision, Clinical Modification* (ICD-10-CM)[8] code for NOWS, P96.1, but

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other states also track infant opioid exposure codes that are given when the infant does not have clinically significant signs of withdrawal.[9,10] Tracking NOWS diagnoses and related exposures is essential for understanding the impact of the opioid epidemic on women and children.[11] However, to accurately assess this impact, it is important to ensure that the correct diagnoses are being tracked.

In October 2018, the ICD-10-CM code P04.14 was introduced to record in utero opioid exposure among newborns.[12] Before the introduction of code P04.14, the less specific code P04.49, which refers to "other" drug exposure, was sometimes used.[9] The introduction of code P04.14 coincided with many hospitals moving to the "eat, sleep, console" (ESC) method of treating NOWS,[13] which recommends that pharmacologic therapy be used only for infants who cannot eat, sleep, or be consoled.[14] This change in treatment protocol could reduce NOWS diagnoses in favor of opioid exposure diagnoses.[15]

How the introduction of the P04.14 code may be affecting the use of the other 2 codes is unclear. The introduction of this code along with updated ESC treatment recommendations adds uncertainty to the interpretation of diagnostic trends. We hypothesized that the introduction of code P04.14 would coincide with a decrease in the use of both P04.49 and P96.1 codes, which could have implications for surveillance of prenatal opioid exposure and NOWS over time.

Methods

We used OPTUM Clinformatics data for the years 2016-2021. OPTUM data include more than 60 million deidentified, commercially insured people in the United States.[16] This study was approved by the institutional review board of Indiana University School of Medicine (no. 1410587167).

Our sample was restricted to infants who received a Z38 code, indicating health insurance at the time of birth, in 2016-2021. This restriction reduced the total sample to 684 048. Because of privacy concerns, we did not have access to complete information on date of birth; we had only the year of birth. We used date of first diagnosis to approximate the birth date. Previous work on this topic, in the *International Classification of Diseases, Ninth Revision* (ICD-9) era, used algorithms to identify iatrogenic cases of opioid withdrawal,[17] but the ICD-10-CM standard has a specific code for iatrogenic withdrawal, P96.2 ("withdrawal symptoms from therapeutic use of drugs in newborn"), to identify these cases.

Our diagnoses of interest were limited to code P96.1 ("neonatal withdrawal symptoms from maternal use of drugs of addiction"), code P04.49 ("newborn affected by maternal use of drugs of addiction"), and code P04.14 ("newborn affected by maternal use of opiates").[18] We tabulated data on diagnoses in the year of the infant's first diagnosis. We did not include diagnoses given ≥28 days after the first diagnosis.[1] Infants given >1 diagnosis in the time frame were categorized as having multiple codes (eg, P96.1 and P04.49). We calculated incidence rates per 1000 births by quarter, by year, and before and after 2018, when code P04.14 was introduced. When we examined the yearly incidence in 2018, we included only the first through the third quarter (January through September), to have a clear demarcation between before and after the introduction of code P04.14. Our data extend only through the third quarter of 2021, because data for the full year were not yet available. We used Stata version 14.1 (StataCorp, LLC) to examine absolute percentage-point change and percentage change in incidence per 1000 births.

Results

The incidence rate per 1000 births of diagnoses using code P04.49 decreased from 2.43 in the third quarter of 2018 to 1.57 in the fourth quarter of 2018 (Figure). Diagnoses using code P96.1 declined from an incidence rate per 1000 births of 1.08 in 2016-2018 to 0.70 in 2019-2021, an absolute decrease of −0.39 (95% CI, −2.44 to 1.67) and a −35.7% (95% CI, −47.6% to −23.8%) change (Table 1). The use of code P04.49 declined from an incidence rate per 1000 births of 2.34 in 2016-2018 to 1.64 in 2019-2021, an absolute decrease of −0.71 (95% CI, −3.11 to 1.70) and a −30.0% (95% CI, −36.4% to −23.7%) change. The incidence rate per 1000 births of multiple codes during the course of treatment increased from 0.55 in 2016-2018 to 0.79 in 2019-2021, an absolute increase of 0.25 (95% CI, −1.60 to 2.10) and a 45.5% (95% CI, 24.8%-66.1%) increase.

In the analysis of the incidence rate per 1000 births of multiple codes, use of codes P04.49 and P96.1 declined from 0.55 in 2016-2018 to 0.36 in 2019-2021, an absolute decrease of −0.18 (95% CI, −1.77 to 1.40) and a −33.5% (95% CI, −51.7% to −15.3%) change (Table 2). The code combinations P04.14 and P96.1, P04.14 and P04.49, and P04.49, P04.14, and P96.1 had incidence rates per 1000 births of 0.21, 0.09, and 0.13, respectively, in 2019-2021.

Discussion

Two trends followed the introduction of code P04.14: the incidence of infant opioid exposure codes exclusively accounted for by codes P96.1 and P04.49 declined, and the incidence of infants receiving multiple ICD-10-CM codes increased. These trends have important implications for NOWS and opioid exposure surveillance. Some state surveillance systems monitor only code P96.1,[12] which could lead to overestimating the reduction in the number of infants born to women who use opioids. It appears that code P04.14 is being used in place of both codes P04.49 and P96.1, which is logical if the clinician knows the infant was exposed to opioids but is not having clinically significant withdrawal symptoms. The largest absolute reduction in incidence occurred in the use of code P04.49, suggesting that physicians are more specifically identifying infants who might previously have been categorized as "affected by maternal use of other drugs."

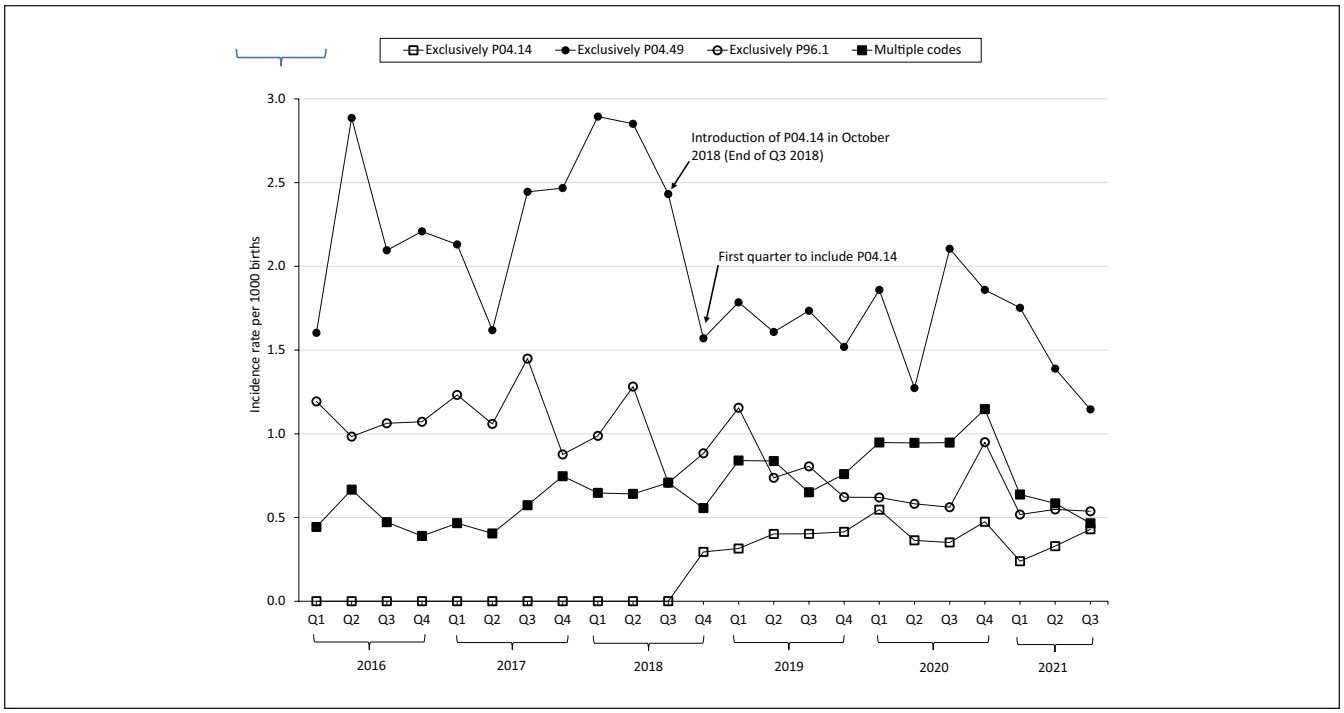

Figure. Trends in ICD-10-CM[8] diagnosis codes for opioid exposure in a sample of privately insured infants born in hospitals (N = 684 048), by quarter (Q), United States, 2016-2021. Diagnosis code definitions are as follows: P04.14, newborn affected by maternal use of opiates; P04.49, newborn (suspected to be) affected by maternal use of other drugs of addiction; P96.1, neonatal withdrawal symptoms from maternal use of drugs of addiction. Multiple codes refer to any combination of the 3 codes from the date of the infant's first diagnosis to 27 days after first diagnosis. Abbreviation: ICD-10-CM, *International Classification of Diseases, Tenth Revision, Clinical Modification*. Data source: OPTUM Clinformatics.[16]

Given the increase in the use of multiple codes after 2018, it is possible that a combination of these codes is being used during the course of treatment. The use of a combination of codes could be a by-product of the introduction of the new code or an indication that clinical diagnostic criteria are changing. Therefore, surveillance systems that monitor opioid exposure in addition to NOWS should consider using all 3 codes and should outline explicit criteria for categorizing infants who receive multiple opioid exposure diagnoses during the surveillance period. These strategies are essential for understanding if the incidence of NOWS is decreasing because fewer infants are being exposed to opioids in utero or because more opioid-exposed infants are being classified as simply exposed (code P04.14) rather than having NOWS (code P96.1). Code P04.49 should be included only if it is examined independently of codes P04.14 and P96.1 because it encompasses all other drug exposures that do not have specific ICD-10-CM codes. Lumping code P04.49 in with codes that are explicitly for opioid exposure or NOWS could increase the risk of false-positive diagnoses.[19]

In general, the use of diagnosis codes to track NOWS and infant in utero opioid exposure is the best way to surveil these conditions, but it is not an exact measurement. Most hospitals do not perform drug tests on every infant, so many opioid-exposed infants may be released without their condition ever being diagnosed. Once an infant with suspected in utero opioid exposure has been identified, he or she is typically monitored for withdrawal by using the Finnegan Neonatal Abstinence Scoring Tool—a tool designed to assess a cluster of symptoms such as a high-pitched cry, an overactive Moro reflex, diarrhea, and other symptoms.[4] When an infant scores above the established score threshold, he or she is generally diagnosed as having NOWS.[20] However, cutoffs for NOWS diagnosis and pharmacologic treatment can vary among hospitals,[21,22] and scoring can vary among health practitioners.[23] Additional training on appropriate Finnegan scoring is sometimes necessary to ensure that infants are scored similarly by all health care personnel.[24]

The increase in the use of multiple codes as diagnoses for opioid-exposed infants may also reflect changes in clinicians' understanding of the appropriateness of opioid exposure diagnoses versus NOWS diagnoses. It is not clear if NOWS should be diagnosed if no treatment is provided.[15] Clinicians must be allowed judgment when diagnosing infants exposed to opioids. However, guidance may be necessary to align their diagnoses with the diagnoses of other medical practitioners to achieve consistency and to aid in uniform surveillance.[25]

Table 1. Incidence rates per 1000 births for *International Classification of Diseases, Tenth Revision, Clinical Modification* diagnosis codes for opioid exposure in a sample of privately insured infants born in hospitals (N = 684 048), United States, 2016-2021[a,b]

Diagnosis code[c]	2016	2017	2018 Q1-Q3[d]	2019	2020	2021 Q1-Q3[e]	Mean 2016-2018 Q3[d]	Mean 2019-2021 Q3[e]	Change[f] (95% CI)	Percentage change[g] (95% CI)
Exclusively P04.14	—	—	—	0.38	0.43	0.34	0	0.41	—	—
Exclusively P04.49	2.21	2.17	2.72	1.66	1.78	1.42	2.34	1.64	−0.71 (−3.11 to 1.70)	−30.0 (−36.4 to −23.7)
Exclusively P96.1	1.08	1.16	0.99	0.83	0.67	0.53	1.08	0.70	−0.39 (−2.44 to 1.67)	−35.7 (−47.6 to −23.8)
Multiple codes	0.49	0.55	0.67	0.77	0.99	0.56	0.55	0.79	0.25 (−1.60 to 2.10)	45.5 (24.8 to 66.1)

Abbreviations: —, not applicable; Q, quarter.
[a] Data source: OPTUM Clinformatics.[16]
[b] Births defined as infants with code Z38 to indicate they had health insurance at the time of birth.
[c] Diagnosis code definitions, per *International Classification of Diseases, Tenth Revision, Clinical Modification*,[8] are as follows: P04.14, newborn affected by maternal use of opiates; P04.49, newborn (suspected to be) affected by maternal use of other drugs of addiction; P96.1, neonatal withdrawal symptoms from maternal use of drugs of addiction. Multiple codes refer to any combination of the 3 codes from the date of the infant's first diagnosis to 27 days after first diagnosis.
[d] Data for 2018 include only Q1-Q3 to establish a clean break between before and after introduction of code P04.14 in October 2018.
[e] 2021 data were available only through Q3.
[f] Defined as (mean of 2019-2021 Q3) − (mean of 2016-2018 Q3). Values may not correspond exactly because of rounding.
[g] Defined as [(mean of 2019-2021) − (mean of 2016-2018 Q3)]/(mean of 2016-2018 Q3). Values may not correspond exactly because of rounding.

Table 2. Incidence rates per 1000 births for *International Classification of Diseases, Tenth Revision, Clinical Modification* diagnosis codes for multiple opioid exposure in a sample of privately insured infants born in hospitals (N = 684 048), United States, 2016-2021[a,b]

Diagnosis code[c]	2016	2017	2018 Q1-Q3[d]	2019	2020	2021 Q1- Q3[e]	Mean 2016-2018 Q3[d]	Mean 2019-2021 Q3[e]	Change[f] (95% CI)	Percentage change[g] (95% CI)
P04.49 and P96.1	0.49	0.55	0.62	0.32	0.45	0.31	0.55	0.36	−0.18 (−1.77 to 1.40)	−33.5 (−51.7 to −15.3)
P04.14 and P96.1	—	—	—	0.23	0.28	0.09	—	0.21	—	—
P04.14 and P04.49	—	—	—	0.08	0.10	0.09	—	0.09	—	—
P04.49, P04.14, and P96.1	—	—	—	0.14	0.17	0.07	—	0.13	—	—

Abbreviations: — not applicable; Q, quarter.
[a] Data source: OPTUM Clinformatics.[16]
[b] Births defined as infants with code Z38 to indicate they had health insurance at the time of birth.
[c] Diagnosis code definitions, per *International Classification of Diseases, Tenth Revision, Clinical Modification*,[8] are as follows: P04.14, newborn affected by maternal use of opiates; P04.49, newborn (suspected to be) affected by maternal use of other drugs of addiction; P96.1, neonatal withdrawal symptoms from maternal use of drugs of addiction.
[d] Data for 2018 include only Q1-Q3 to establish a clean break between before and after introduction of code P04.14 in October 2018.
[e] 2021 data were available only through Q3.
[f] Defined as (mean of 2019-2021 Q3) − (mean of 2016-2018 Q3). Values may not correspond exactly because of rounding.
[g] Defined as [(mean of 2019-2021) − (mean of 2016-2018 Q3)]/(mean of 2016-2018 Q3). Values may not correspond exactly because of rounding.

Surprisingly, the incidence of infants with opioid-related codes decreased during the study period, but the number of opioid overdoses in the United States increased during the same period.[26] Our data showed an increase in the incidence of NOWS and opioid exposure through 2018, which aligns with previous work that tracked the incidence of NOWS through 2017.[27] Our data then showed a decrease in the incidence of NOWS that began in 2019. At least 1 other data source noted a slight decrease in NOWS diagnoses beginning in 2018,[28] but that report did not discuss reasons for the decrease. Historically, most cases of NOWS have been found among individuals with public health insurance,[27] and our data consisted of individuals with private health insurance. It is possible that the reduction in diagnoses of NOWS and opioid exposure was due to a further shift in the demographic characteristics of the population affected by the opioid epidemic. A shift in the affected population is not likely to affect diagnostic practices, so the results of this study are still worth examining in a Medicaid population.

An important consideration for the continued reduction in NOWS diagnoses that we found in 2020 is the COVID-19 pandemic.[29] During the pandemic, women and infants experienced expedited discharges to limit potential virus exposures.[30] Recent work showed that a large percentage of mothers with opioid use disorder were not identified during pregnancy,[31] so medical professionals did not know to screen infants for opioid withdrawal symptoms after birth. Thus, many infants with NOWS may have been diagnosed and treated because a medical practitioner independently identified withdrawal symptoms in the hospital and performed the appropriate

screening before the infant was discharged. The expedited discharges could have affected diagnosis rates if infants began withdrawing after discharge and were therefore not identified. It is essential that future work dig deeper into these trends to understand whether fewer infants are being exposed to opioids in utero relative to previous years or infants are simply less likely to be diagnosed with opioid exposure or NOWS. Additional studies should also investigate these trends among Medicaid beneficiaries.

Limitations

Our study had several potential limitations. First, it was limited by our inability to control for the use of ESC protocol, which increased during the period observed.[13] ESC reduces the use of pharmacologic therapy by recommending treatment be given only to infants who cannot eat, sleep, or be consoled. Physicians may use code P04.14 in place of code P96.1 if the infant does not have withdrawal symptoms severe enough to require pharmacologic treatment[15] and, as a result, fewer infants may be receiving a NOWS diagnosis. Unfortunately, our dataset did not contain information about whether ESC was used in the hospitals where the infants were born, so we could not control for the use of ESC treatment protocol directly. Second, we were limited in the conclusions we could draw regarding population trends because our sample contains only privately insured infants. Third, the COVID-19 pandemic may have affected the identification of opioid-exposed infants because of expedited discharge times, but we had no way of controlling for this factor in our analysis.

Conclusion

The introduction of ICD-10-CM code P04.14 in 2018 reduced the proportion of total opioid exposure codes accounted for by codes P96.1 and P04.49 in a sample of infants with private health insurance in the United States. The way in which states have attempted to quantify the incidence of neonatal opioid exposure varies widely,[9] and the introduction of code P04.14 further complicates this endeavor. However, this complication may be necessary and productive because prenatal opioid exposure is associated with birth defects[6] and developmental delays[7] even when clinically significant signs of withdrawal are not documented. Therefore, correctly identifying as many of the opioid-exposed infants who may have previously been identified as P04.49 (the "other drugs" category) is a worthwhile objective. The timing of the introduction of code P04.14 coincided with increased use of the ESC method for determining the need for pharmacologic therapy,[13] which could also affect the total numbers of opioid exposure diagnoses,[14] the use of code P04.14 in place of code P96.1, and the use of multiple opioid exposure codes during the course of treatment. To obtain the most accurate measure of neonatal opioid exposure, states should monitor the use of codes P96.1 and P04.14 and should consider monitoring code P04.49 if resources are available.

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