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The following report(s) provides findings from an FDA-initiated query using Sentinel. While Sentinel queries may be undertaken to assess potential medical product safety risks, they may also be initiated for various other reasons. Some examples include determining a rate or count of an identified health outcome of interest, examining medical product use, exploring the feasibility of future, more detailed analyses within Sentinel, and seeking to better understand Sentinel capabilities.

Data obtained through Sentinel are intended to complement other types of evidence such as preclinical studies, clinical trials, postmarket studies, and adverse event reports, all of which are used by FDA to inform regulatory decisions regarding medical product safety. The information contained in this report is provided as part of FDA's commitment to place knowledge acquired from Sentinel in the public domain as soon as possible. Any public health actions taken by FDA regarding products involved in Sentinel queries will continue to be communicated through

FDA wants to emphasize that the fact that FDA has initiated a query involving a medical product and is reporting findings related to that query does not mean that FDA is suggesting health care practitioners should change their prescribing practices for the medical product or that patients taking the medical product should stop using it. Patients who have questions about the use of an identified medical product should contact their health care

The following report contains a description of the request, request specifications, and results from the modular program run(s).

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## Overview for Request cder\_ahr\_wp011

**Request ID:** cder\_ahr\_wp011\_hca\_v01

**Request Description:** The objective of this request was to identify use of typical and atypical antipsychotics among neonates during inpatient encounters using Hospital Corporation of America (HCA) Healthcare data.

**Sentinel Modular Program Tool Used:** Inpatient Encounter Tool, Version 1.0.0

**Data Source:** HCA's Sentinel data (ETL 3.0) from July 1, 2011 - September 30, 2017 were included in this report. This request was distributed on August 15, 2019. See Appendix A for a list of dates of available data.

**Study Cohort, Denominator A:** We used the encounter data from HCA Sentinel Common Data Model (SCDM) to identify neonates less than 180 days of age who were admitted to the hospital. We required the length of stay to be greater than three days.

**Study Cohort, Denominator B:** We used the encounter data from HCA SCDM to identify neonates less than 180 days of age who were admitted to the hospital. There were no minimum length of stay requirements.

**Medical Product Assessment:** Among the study cohorts, we identified administrations of typical and atypical antipsychotics. We characterized the duration of therapy (days) and the frequency of antipsychotic administrations overall and by generic drug name. We identified antipsychotics mapping hospital-specific drug mnemonics at each facility and using National Drug Codes (NDC). See Appendix B for a list of brand and generic drug names used to define typical and atypical antipsychotics.

**Patient Demographics and Encounter Characteristics:** We stratified neonate patients by age at admission, sex, and encounter features including admission year and length of stay. Age groups at admission included the following: 0-10, 11-20, 21-30, 31-60, 61-90, 91-120, 121-179 days.

**Limitations:** Algorithms to define exposures are imperfect and may be misclassified.

**Notes:** Please contact the Sentinel Operations Center Query Fulfillment Team ([qf@sentinelssystem.org](mailto:qf@sentinelssystem.org)) for questions and to provide comments/suggestions for future enhancements to this document.

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**Table 1. Attrition Table**

<b>Criteria</b>	<b>Description</b>	<b>Remaining Number of Encounters/Patients/Facilities</b>	<b>Percent*</b>	<b>Excluded Number of Encounters/Patients/Facilities</b>	<b>Percent*</b>
1	Total number of encounters/patients/facilities	84,680,947/25,887,998/175			
2	Total number of encounters/patients/facilities restricted to encounter= Inpatient	12,145,437/7,535,580/173	14.3/29.1/98.9	72,535,510/18,352,418/2	85.7/70.9/1.1
3	Total number of Inpatient encounters/patients/facilities with age <180 days at admission	1,408,663/1,366,019/125	11.6/18.1/72.3	10,736,774/6,169,561/48	88.4/81.9/27.7
4	Inpatient encounters/patients/facilities with length of stay >3 days	482,053/471,895/120	34.2/34.5/96.0	926,610/894,124/5	65.8/65.5/4.0

\*Percentages are estimated using the total encounter/patients/facilities reported in the previous step

**Table 2a. Characteristics of Inpatient Encounters in Infants <180 Days and Length of Stay >3 Days with Atypical and Typical Antipsychotic Use and All Inpatient Encounters Among Infants <180 Days and Length of Stay >3 Days between July 1, 2011 and September 30, 2017\***

<b>Encounter Characteristics</b>	<b>All Inpatient Encounters in Infants</b>	<b>Percent All Inpatient Encounters in Infants</b>	<b>Inpatient Encounters in Infants Receiving Any Antipsychotic</b>	<b>Percent Inpatient Encounters in Infants Receiving Any Antipsychotic</b>	<b>Inpatient Encounters in Infants Receiving Atypical Antipsychotic</b>	<b>Percent Inpatient Encounters in Infants Receiving Atypical Antipsychotic</b>	<b>Inpatient Encounters in Infants Receiving Typical Antipsychotic</b>	<b>Percent Inpatient Encounters in Infants Receiving Typical Antipsychotic</b>
Total inpatient encounters	482,053	100%	29	100%	3	100%	29	100%
Total patients associated with inpatient encounters	471,895	100%	29	100%	3	100%	29	100%
Number of facilities associated with inpatient encounters	120	100%	4	100%	2	100%	4	100%
Age (days) (median, min, max)	1, 1, 179	N/A	68, 1, 178	N/A	45, 1, 117	N/A	71, 1, 178	N/A
00 - 10 Days	450,236	93%	12	41%	1	33%	12	41%
11 - 20 Days	4,051	1%	0	0%	0	0%	0	0%
21 - 30 Days	3,693	1%	0	0%	0	0%	0	0%
31 - 60 Days	8,429	2%	1	3%	1	33%	1	3%
61 - 90 Days	5,424	1%	4	14%	0	0%	4	14%
91 - 120 Days	3,929	1%	2	7%	1	33%	2	7%
121 - 179 Days	6,291	1%	10	34%	0	0%	10	34%
Sex								
Female	223,491	46%	13	45%	2	67%	13	45%
Male	258,164	54%	16	55%	1	33%	16	55%
Unknown	398	0.1%	0	0%	0	0%	0	0%
Admission year								
2011	38,660	8%	0	0%	0	0%	0	0%
2012	78,325	16%	1	3%	1	33%	1	3%
2013	75,736	16%	3	10%	0	0%	3	10%
2014	78,089	16%	7	24%	0	0%	7	24%
2015	79,221	16%	3	10%	0	0%	3	10%
2016	77,694	16%	11	38%	2	67%	11	38%
2017	54,328	11%	4	14%	0	0%	4	14%
Length of stay median (min, max, standard deviation)	4.0 (4,484,16.14)	N/A	114.0 (5,408,82.92)	N/A	132.0 (5,215,105.8)	N/A	111.0 (5,408,82.55)	N/A

**Table 2a. Characteristics of Inpatient Encounters in Infants <180 Days and Length of Stay >3 Days with Atypical and Typical Antipsychotic Use and All Inpatient Encounters Among Infants <180 Days and Length of Stay >3 Days between July 1, 2011 and September 30, 2017\***

Encounter Characteristics	All Inpatient Encounters in Infants	Percent All Inpatient Encounters in Infants	Inpatient Encounters in Infants Receiving Any Antipsychotic	Percent Inpatient Encounters in Infants Receiving Any Antipsychotic	Inpatient Encounters in Infants Receiving Atypical Antipsychotic	Percent Inpatient Encounters in Infants Receiving Atypical Antipsychotic	Inpatient Encounters in Infants Receiving Typical Antipsychotic	Percent Inpatient Encounters in Infants Receiving Typical Antipsychotic
<b>All antipsychotic medications</b>								
Days of therapy of antipsychotic administration during inpatient stay, median, (min, max, standard deviation)			3.5 (1,63,15.57)	N/A	18.0 (2,43,20.66)	N/A	3.0 (1,63,14.98)	N/A
Number of inpatient encounters with number of days of therapy for antipsychotic administration <sup>1</sup>								
1 day(s)			10	34%	0	0%	10	34%
2 day(s)			5	17%	1	33%	4	14%
3 day(s)			1	3%	0	0%	1	3%
4 day(s)			3	10%	0	0%	3	10%
5 day(s)			2	7%	0	0%	2	7%
7 day(s)			2	7%	0	0%	2	7%
10 day(s)			1	3%	0	0%	1	3%
17 day(s)			1	3%	0	0%	1	3%
18 day(s)			1	3%	1	33%	0	0%
19 day(s)			1	3%	0	0%	1	3%
25 day(s)			1	3%	0	0%	1	3%
28 day(s)			1	3%	0	0%	1	3%
43 day(s)			1	3%	1	33%	0	0%
49 day(s)			1	3%	0	0%	1	3%
63 day(s)			1	3%	0	0%	1	3%
Frequency of antipsychotic administration during inpatient stay, median (min, max, standard deviation)			5.0 (1,160,35.27)	N/A	18.0 (3,53,25.66)	N/A	5.0 (1,160,36.42)	N/A

**Table 2a. Characteristics of Inpatient Encounters in Infants <180 Days and Length of Stay >3 Days with Atypical and Typical Antipsychotic Use and All Inpatient Encounters Among Infants <180 Days and Length of Stay >3 Days between July 1, 2011 and September 30, 2017\***

Encounter Characteristics	All Inpatient Encounters in Infants	Percent All Inpatient Encounters in Infants	Inpatient Encounters in Infants Receiving Any Antipsychotic	Percent Inpatient Encounters in Infants Receiving Any Antipsychotic	Inpatient Encounters in Infants Receiving Atypical Antipsychotic	Percent Inpatient Encounters in Infants Receiving Atypical Antipsychotic	Inpatient Encounters in Infants Receiving Typical Antipsychotic	Percent Inpatient Encounters in Infants Receiving Typical Antipsychotic	
Number of inpatient encounters with frequency of administration of antipsychotics									
1			9	31%	0	0%	9	31%	
2			4	14%	0	0%	4	14%	
3			1	3%	1	33%	0	0%	
4			1	3%	0	0%	1	3%	
5			2	7%	0	0%	2	7%	
6			1	3%	0	0%	1	3%	
7			1	3%	0	0%	1	3%	
8			1	3%	0	0%	1	3%	
10			1	3%	0	0%	1	3%	
11			2	7%	0	0%	2	7%	
16			1	3%	0	0%	1	3%	
18			1	3%	1	33%	0	0%	
28			2	7%	0	0%	2	7%	
39			1	3%	0	0%	1	3%	
53			1	3%	1	33%	0	0%	
56			1	3%	0	0%	1	3%	
119			1	3%	0	0%	1	3%	
160			1	3%	0	0%	1	3%	
<b>Antipsychotics by generic name of drug administered</b>									
<b>CHLORPROMAZINE HCL</b>								2	7%
Days of therapy of antipsychotic administration during inpatient stay, median (min, max, standard deviation)								33.5 (4,63,41.72)	N/A

**Table 2a. Characteristics of Inpatient Encounters in Infants <180 Days and Length of Stay >3 Days with Atypical and Typical Antipsychotic Use and All Inpatient Encounters Among Infants <180 Days and Length of Stay >3 Days between July 1, 2011 and September 30, 2017\***

<b>Encounter Characteristics</b>	<b>All Inpatient Encounters in Infants</b>	<b>Percent All Inpatient Encounters in Infants</b>	<b>Inpatient Encounters in Infants Receiving Any Antipsychotic</b>	<b>Percent Inpatient Encounters in Infants Receiving Any Antipsychotic</b>	<b>Inpatient Encounters in Infants Receiving Atypical Antipsychotic</b>	<b>Percent Inpatient Encounters in Infants Receiving Atypical Antipsychotic</b>	<b>Inpatient Encounters in Infants Receiving Typical Antipsychotic</b>	<b>Percent Inpatient Encounters in Infants Receiving Typical Antipsychotic</b>
Number of inpatient encounters with number of days of therapy for antipsychotic administration								
4							1	50%
63							1	50%
Frequency of antipsychotic administration during inpatient stay, median (min, max, standard deviation)							85.5 (11,160,105.4)	N/A
Number of inpatient encounters with frequency of administration of antipsychotics								
11							1	50%
160							1	50%
<b>HALOPERIDOL</b>							12	41%
Days of therapy of antipsychotic administration during inpatient stay, median (min, max, standard deviation)							4.5 (1,36,11.72)	N/A
Number of inpatient encounters with number of days of therapy for antipsychotic administration								
1							3	25%
2							1	8%
3							2	17%
6							1	8%
10							1	8%
13							1	8%
19							1	8%
28							1	8%
36							1	8%
Frequency of antipsychotic administration during inpatient stay, median (min, max, standard deviation)							7.5 (1,74,22.32)	N/A

**Table 2a. Characteristics of Inpatient Encounters in Infants <180 Days and Length of Stay >3 Days with Atypical and Typical Antipsychotic Use and All Inpatient Encounters Among Infants <180 Days and Length of Stay >3 Days between July 1, 2011 and September 30, 2017\***

Encounter Characteristics	All Inpatient Encounters in Infants	Percent All Inpatient Encounters in Infants	Inpatient Encounters in Infants Receiving Any Antipsychotic	Percent Inpatient Encounters in Infants Receiving Any Antipsychotic	Inpatient Encounters in Infants Receiving Atypical Antipsychotic	Percent Inpatient Encounters in Infants Receiving Atypical Antipsychotic	Inpatient Encounters in Infants Receiving Typical Antipsychotic	Percent Inpatient Encounters in Infants Receiving Typical Antipsychotic
Number of inpatient encounters with frequency of administration of antipsychotics								
1							2	17%
2							1	8%
3							1	8%
4							1	8%
6							1	8%
9							1	8%
10							1	8%
27							1	8%
28							1	8%
43							1	8%
74							1	8%
<b>HALOPERIDOL LACTATE</b>							23	79%
Days of therapy of antipsychotic administration during inpatient stay, median (min, max, standard deviation)							2.0 (1,13,3.37)	N/A
Number of inpatient encounters with number of days of therapy for antipsychotic administration								
1							9	39%
2							4	17%
3							2	9%
5							3	13%
6							1	4%
7							2	9%
11							1	4%
13							1	4%

**Table 2a. Characteristics of Inpatient Encounters in Infants <180 Days and Length of Stay >3 Days with Atypical and Typical Antipsychotic Use and All Inpatient Encounters Among Infants <180 Days and Length of Stay >3 Days between July 1, 2011 and September 30, 2017\***

<b>Encounter Characteristics</b>	<b>All Inpatient Encounters in Infants</b>	<b>Percent All Inpatient Encounters in Infants</b>	<b>Inpatient Encounters in Infants Receiving Any Antipsychotic</b>	<b>Percent Inpatient Encounters in Infants Receiving Any Antipsychotic</b>	<b>Inpatient Encounters in Infants Receiving Atypical Antipsychotic</b>	<b>Percent Inpatient Encounters in Infants Receiving Atypical Antipsychotic</b>	<b>Inpatient Encounters in Infants Receiving Typical Antipsychotic</b>	<b>Percent Inpatient Encounters in Infants Receiving Typical Antipsychotic</b>
Frequency of antipsychotic administration during inpatient stay, median (min, max, standard deviation)							2.0 (1,45,9.77)	N/A
Number of inpatient encounters with frequency of administration of antipsychotics								
1							9	39%
2							3	13%
3							1	4%
4							1	4%
5							1	4%
6							1	4%
8							1	4%
10							1	4%
11							1	4%
12							1	4%
13							1	4%
19							1	4%
45							1	4%
<b>OLANZAPINE</b>					3	100%		
Days of therapy of antipsychotic administration during inpatient stay, median (min, max, standard deviation)					18.0 (2,43,20.66)	N/A		
Number of inpatient encounters with number of days of therapy for antipsychotic administration								
2					1	33%		
18					1	33%		
43					1	33%		

**Table 2a. Characteristics of Inpatient Encounters in Infants <180 Days and Length of Stay >3 Days with Atypical and Typical Antipsychotic Use and All Inpatient Encounters Among Infants <180 Days and Length of Stay >3 Days between July 1, 2011 and September 30, 2017\***

<b>Encounter Characteristics</b>	<b>All Inpatient Encounters in Infants</b>	<b>Percent All Inpatient Encounters in Infants</b>	<b>Inpatient Encounters in Infants Receiving Any Antipsychotic</b>	<b>Percent Inpatient Encounters in Infants Receiving Any Antipsychotic</b>	<b>Inpatient Encounters in Infants Receiving Atypical Antipsychotic</b>	<b>Percent Inpatient Encounters in Infants Receiving Atypical Antipsychotic</b>	<b>Inpatient Encounters in Infants Receiving Typical Antipsychotic</b>	<b>Percent Inpatient Encounters in Infants Receiving Typical Antipsychotic</b>
Frequency of antipsychotic administration during inpatient stay, median (min, max, standard deviation)					18.0 (3,53,25.66)	N/A		
Number of inpatient encounters with frequency of administration of antipsychotics								
3					1	33%		
18					1	33%		
53					1	33%		

\*For all inpatients encounters among infants, admission date was required to occurs from July 1, 2011 through September 30, 2017 and discharge date of inpatient stay on or earlier than September 30, 2017

<sup>1</sup>Please note that summation of inpatient encounters with days of therapy for antipsychotic administration, n=32, is greater than total inpatient encounters, n=29, since 3 patients received both typical and atypical antipsychotic during their inpatient stay

**Table 2b. Characteristics of Inpatient Encounters in Infants <180 Days with Atypical and Typical Antipsychotic Use and All Inpatient Encounters Among Infants <180 Days between July 1, 2011 and September 30, 2017\***

<b>Encounter Characteristics</b>	<b>All Inpatient Encounters in Infants</b>	<b>Percent All Inpatient Encounters in Infants</b>	<b>Inpatient Encounters in Infants Receiving Any Antipsychotic</b>	<b>Percent Inpatient Encounters in Infants Receiving Any Antipsychotic</b>	<b>Inpatient Encounters in Infants Receiving Atypical Antipsychotic</b>	<b>Percent Inpatient Encounters in Infants Receiving Atypical Antipsychotic</b>	<b>Inpatient Encounters in Infants Receiving Typical Antipsychotic</b>	<b>Percent Inpatient Encounters in Infants Receiving Typical Antipsychotic</b>
Total inpatient encounters	1,408,663	100%	29	100%	3	100%	29	100%
Total patients associated with inpatient encounters	1,366,019	100%	29	100%	3	100%	29	100%
Number of facilities associated with inpatient encounters	125	100%	4	100%	2	100%	4	100%
Age (days) (median, min, max)	1, 1, 179	N/A	68, 1, 178	N/A	45, 1, 117	N/A	71, 1, 178	N/A
00 - 10 Days	1,345,627	96%	12	41%	1	33%	12	41%
11 - 20 Days	7,091	1%	0	0%	0	0%	0	0%
21 - 30 Days	7,173	1%	0	0%	0	0%	0	0%
31 - 60 Days	17,323	1%	1	3%	1	33%	1	3%
61 - 90 Days	10,828	1%	4	14%	0	0%	4	14%
91 - 120 Days	7,922	1%	2	7%	1	33%	2	7%
121 - 179 Days	12,699	1%	10	34%	0	0%	10	34%
Sex								
Female	682,217	48%	13	45%	2	67%	13	45%
Male	725,049	51%	16	55%	1	33%	16	55%
Unknown	1,397	0.1%	0	0%	0	0%	0	0%
Admission year								
2011	113,174	8%	0	0%	0	0%	0	0%
2012	224,980	16%	1	3%	1	33%	1	3%
2013	222,361	16%	3	10%	0	0%	3	10%
2014	227,428	16%	7	24%	0	0%	7	24%
2015	230,182	16%	3	10%	0	0%	3	10%
2016	228,231	16%	11	38%	2	67%	11	38%
2017	162,307	12%	4	14%	0	0%	4	14%
Length of stay median (min, max, standard deviation)	3.0 (1,484,9.99)	N/A	114.0 (5,408,82.92)	N/A	132.0 (5,215,105.8)	N/A	111.0 (5,408,82.55)	N/A

**Table 2b. Characteristics of Inpatient Encounters in Infants <180 Days with Atypical and Typical Antipsychotic Use and All Inpatient Encounters Among Infants <180 Days between July 1, 2011 and September 30, 2017\***

Encounter Characteristics	All Inpatient Encounters in Infants	Percent All Inpatient Encounters in Infants	Inpatient Encounters in Infants Receiving Any Antipsychotic	Percent Inpatient Encounters in Infants Receiving Any Antipsychotic	Inpatient Encounters in Infants Receiving Atypical Antipsychotic	Percent Inpatient Encounters in Infants Receiving Atypical Antipsychotic	Inpatient Encounters in Infants Receiving Typical Antipsychotic	Percent Inpatient Encounters in Infants Receiving Typical Antipsychotic
<b>All antipsychotic medications</b>								
Days of therapy of antipsychotic administration during inpatient stay, median, (min, max, standard deviation)			3.5 (1,63,15.57)	N/A	18.0 (2,43,20.66)	N/A	3.0 (1,63,14.98)	N/A
Number of inpatient encounters with number of days of therapy for antipsychotic administration <sup>1</sup>								
1 day(s)			10	34%	0	0%	10	34%
2 day(s)			5	17%	1	33%	4	14%
3 day(s)			1	3%	0	0%	1	3%
4 day(s)			3	10%	0	0%	3	10%
5 day(s)			2	7%	0	0%	2	7%
7 day(s)			2	7%	0	0%	2	7%
10 day(s)			1	3%	0	0%	1	3%
17 day(s)			1	3%	0	0%	1	3%
18 day(s)			1	3%	1	33%	0	0%
19 day(s)			1	3%	0	0%	1	3%
25 day(s)			1	3%	0	0%	1	3%
28 day(s)			1	3%	0	0%	1	3%
43 day(s)			1	3%	1	33%	0	0%
49 day(s)			1	3%	0	0%	1	3%
63 day(s)			1	3%	0	0%	1	3%
Frequency of administrations during an inpatient encounter, median (min, max, standard deviation)			5.0 (1,160,35.27)	N/A	18.0 (3,53,25.66)	N/A	5.0 (1,160,36.42)	N/A

**Table 2b. Characteristics of Inpatient Encounters in Infants <180 Days with Atypical and Typical Antipsychotic Use and All Inpatient Encounters Among Infants <180 Days between July 1, 2011 and September 30, 2017\***

<b>Encounter Characteristics</b>	<b>All Inpatient Encounters in Infants</b>	<b>Percent All Inpatient Encounters in Infants</b>	<b>Inpatient Encounters in Infants Receiving Any Antipsychotic</b>	<b>Percent Inpatient Encounters in Infants Receiving Any Antipsychotic</b>	<b>Inpatient Encounters in Infants Receiving Atypical Antipsychotic</b>	<b>Percent Inpatient Encounters in Infants Receiving Atypical Antipsychotic</b>	<b>Inpatient Encounters in Infants Receiving Typical Antipsychotic</b>	<b>Percent Inpatient Encounters in Infants Receiving Typical Antipsychotic</b>
Number of inpatient encounters with frequency of administration of antipsychotics								
1			9	31%	0	0%	9	31%
2			4	14%	0	0%	4	14%
3			1	3%	1	33%	0	0%
4			1	3%	0	0%	1	3%
5			2	7%	0	0%	2	7%
6			1	3%	0	0%	1	3%
7			1	3%	0	0%	1	3%
8			1	3%	0	0%	1	3%
10			1	3%	0	0%	1	3%
11			2	7%	0	0%	2	7%
16			1	3%	0	0%	1	3%
18			1	3%	1	33%	0	0%
28			2	7%	0	0%	2	7%
39			1	3%	0	0%	1	3%
53			1	3%	1	33%	0	0%
56			1	3%	0	0%	1	3%
119			1	3%	0	0%	1	3%
160			1	3%	0	0%	1	3%
<b>Antipsychotics by generic name of drug administered</b>								
<b>CHLORPROMAZINE HCL</b>							2	7%
Days of therapy of antipsychotic administration during inpatient stay, median (min, max, standard deviation)							33.5 (4,63,41.72)	N/A

**Table 2b. Characteristics of Inpatient Encounters in Infants <180 Days with Atypical and Typical Antipsychotic Use and All Inpatient Encounters Among Infants <180 Days between July 1, 2011 and September 30, 2017\***

Encounter Characteristics	All Inpatient Encounters in Infants	Percent All Inpatient Encounters in Infants	Inpatient Encounters in Infants Receiving Any Antipsychotic	Percent Inpatient Encounters in Infants Receiving Any Antipsychotic	Inpatient Encounters in Infants Receiving Atypical Antipsychotic	Percent Inpatient Encounters in Infants Receiving Atypical Antipsychotic	Inpatient Encounters in Infants Receiving Typical Antipsychotic	Percent Inpatient Encounters in Infants Receiving Typical Antipsychotic
Number of inpatient encounters with number of days of therapy for antipsychotic administration								
4							1	50%
63							1	50%
Frequency of antipsychotic administration during inpatient stay, median (min, max, standard deviation)							85.5 (11,160,105.4)	N/A
Number of inpatient encounters with frequency of administration of antipsychotics								
11							1	50%
160							1	50%
<b>HALOPERIDOL</b>							12	41%
Days of therapy of antipsychotic administration during inpatient stay, median (min, max, standard deviation)							4.5 (1,36,11.72)	N/A
Number of inpatient encounters with number of days of therapy for antipsychotic administration								
1							3	25%
2							1	8%
3							2	17%
6							1	8%
10							1	8%
13							1	8%
19							1	8%
28							1	8%
36							1	8%
Frequency of antipsychotic administration during inpatient stay, median (min, max, standard deviation)							7.5 (1,74,22.32)	N/A

**Table 2b. Characteristics of Inpatient Encounters in Infants <180 Days with Atypical and Typical Antipsychotic Use and All Inpatient Encounters Among Infants <180 Days between July 1, 2011 and September 30, 2017\***

Encounter Characteristics	All Inpatient Encounters in Infants	Percent All Inpatient Encounters in Infants	Inpatient Encounters in Infants Receiving Any Antipsychotic	Percent Inpatient Encounters in Infants Receiving Any Antipsychotic	Inpatient Encounters in Infants Receiving Atypical Antipsychotic	Percent Inpatient Encounters in Infants Receiving Atypical Antipsychotic	Inpatient Encounters in Infants Receiving Typical Antipsychotic	Percent Inpatient Encounters in Infants Receiving Typical Antipsychotic
Number of inpatient encounters with frequency of administration of antipsychotics								
1							2	17%
2							1	8%
3							1	8%
4							1	8%
6							1	8%
9							1	8%
10							1	8%
27							1	8%
28							1	8%
43							1	8%
74							1	8%
<b>HALOPERIDOL LACTATE</b>							23	79%
Days of therapy of antipsychotic administration during inpatient stay, median (min, max, standard deviation)							2.0 (1,13,3.37)	N/A
Number of inpatient encounters with number of days of therapy for antipsychotic administration								
1							9	39%
2							4	17%
3							2	9%
5							3	13%
6							1	4%
7							2	9%
11							1	4%
13							1	4%

**Table 2b. Characteristics of Inpatient Encounters in Infants <180 Days with Atypical and Typical Antipsychotic Use and All Inpatient Encounters Among Infants <180 Days between July 1, 2011 and September 30, 2017\***

Encounter Characteristics	All Inpatient Encounters in Infants	Percent All Inpatient Encounters in Infants	Inpatient Encounters in Infants Receiving Any Antipsychotic	Percent Inpatient Encounters in Infants Receiving Any Antipsychotic	Inpatient Encounters in Infants Receiving Atypical Antipsychotic	Percent Inpatient Encounters in Infants Receiving Atypical Antipsychotic	Inpatient Encounters in Infants Receiving Typical Antipsychotic	Percent Inpatient Encounters in Infants Receiving Typical Antipsychotic
Frequency of antipsychotic administration during inpatient stay, median (min, max, standard deviation)							2.0 (1,45,3.37)	N/A
Number of inpatient encounters with frequency of administration of antipsychotics								
1							9	39%
2							3	13%
3							1	4%
4							1	4%
5							1	4%
6							1	4%
8							1	4%
10							1	4%
11							1	4%
12							1	4%
13							1	4%
19							1	4%
45							1	4%
<b>OLANZAPINE</b>					3	100%		
Days of therapy of antipsychotic administration during inpatient stay, median (min, max, standard deviation)					18.0 (2,43,20.66)	N/A		
Number of inpatient encounters with number of days of therapy for antipsychotic administration								
2					1	33%		
18					1	33%		
43					1	33%		

**Table 2b. Characteristics of Inpatient Encounters in Infants <180 Days with Atypical and Typical Antipsychotic Use and All Inpatient Encounters Among Infants <180 Days between July 1, 2011 and September 30, 2017\***

<b>Encounter Characteristics</b>	<b>All Inpatient Encounters in Infants</b>	<b>Percent All Inpatient Encounters in Infants</b>	<b>Inpatient Encounters in Infants Receiving Any Antipsychotic</b>	<b>Percent Inpatient Encounters in Infants Receiving Any Antipsychotic</b>	<b>Inpatient Encounters in Infants Receiving Atypical Antipsychotic</b>	<b>Percent Inpatient Encounters in Infants Receiving Atypical Antipsychotic</b>	<b>Inpatient Encounters in Infants Receiving Typical Antipsychotic</b>	<b>Percent Inpatient Encounters in Infants Receiving Typical Antipsychotic</b>
Frequency of antipsychotic administration during inpatient stay, median (min, max, standard deviation)					18.0 (3,53,25.66)	N/A		
Number of inpatient encounters with frequency of administration of antipsychotics								
3					1	33%		
18					1	33%		
53					1	33%		

\*For all inpatients encounters among infants, admission date was required to occurs from 07/01/2011 through 09/30/2017 and discharge date of inpatient stay on or earlier than 09/30/2017

<sup>1</sup>Please note that summation of inpatient encounters with days of therapy for antipsychotic administration, n=32, is greater than total inpatient encounters, n=29, since 3 patients received both typical and atypical antipsychotic during their inpatient stay.

**Table 3a. Counts for Value-Combinations of Generic Drug Name, Route of Administration, Dose Strength, Unit of Measurement, and Type of Antipsychotic Administered During Inpatient Stay Among Infants <180 Days and Length of Stay >3 Days**

Number of Inpatient Encounters Among Infants <180 Days and Length of Stay >3 Days	Frequency of Antipsychotic Administrations	Generic Drug Name	Type of Antipsychotic			
			Medication (Typical, Atypical)	Route of Administration <sup>1</sup>	Dose Strength	Unit of Measurement
1	10	CHLORPROMAZINE HCL	Typical	PER TUBE	7	MG
1	3	CHLORPROMAZINE HCL	Typical	PO	5	MG
1	11	CHLORPROMAZINE HCL	Typical	PO	6.25	MG
1	147	CHLORPROMAZINE HCL	Typical	PO	10	MG
1	19	HALOPERIDOL	Typical	FEED-TUBE	0.1	MG
1	1	HALOPERIDOL	Typical	FEED-TUBE	0.15	MG
1	13	HALOPERIDOL	Typical	FEED-TUBE	0.2	MG
1	4	HALOPERIDOL	Typical	FEED-TUBE	0.3	MG
1	5	HALOPERIDOL	Typical	FEED-TUBE	0.3	MG
1	9	HALOPERIDOL	Typical	FEED-TUBE	0.3	MG
1	43	HALOPERIDOL	Typical	FEED-TUBE	0.3	MG
1	9	HALOPERIDOL	Typical	FEED-TUBE	0.4	MG
1	11	HALOPERIDOL	Typical	FEED-TUBE	0.5	MG
1	27	HALOPERIDOL	Typical	FEED-TUBE	0.5	MG
1	1	HALOPERIDOL	Typical	FEED-TUBE	0.6	MG
1	22	HALOPERIDOL	Typical	FEED-TUBE	0.6	MG
1	2	HALOPERIDOL	Typical	IV	4	MG
1	28	HALOPERIDOL	Typical	PO	0.1	MG
1	1	HALOPERIDOL	Typical	PO	0.3	MG
1	3	HALOPERIDOL	Typical	PO	0.45	MG
1	1	HALOPERIDOL	Typical	TU	0.25	MG
1	9	HALOPERIDOL	Typical	TU	0.5	MG
1	1	HALOPERIDOL LACTATE	Typical	.ROUTE	0.1	MG
1	1	HALOPERIDOL LACTATE	Typical	.ROUTE	0.15	MG
1	6	HALOPERIDOL LACTATE	Typical	IV	0.5	MG
1	11	HALOPERIDOL LACTATE	Typical	IVPed	0.1	MG
1	2	HALOPERIDOL LACTATE	Typical	IVPed	0.15	MG
2	1	HALOPERIDOL LACTATE	Typical	IVPed	0.2	MG
1	8	HALOPERIDOL LACTATE	Typical	IVPed	0.2	MG
1	10	HALOPERIDOL LACTATE	Typical	IVPed	0.2	MG
1	19	HALOPERIDOL LACTATE	Typical	IVPed	0.25	MG
1	1	HALOPERIDOL LACTATE	Typical	IVPed	0.27	MG
1	1	HALOPERIDOL LACTATE	Typical	IVPed	0.3	MG
3	2	HALOPERIDOL LACTATE	Typical	IVPed	0.3	MG
1	8	HALOPERIDOL LACTATE	Typical	IVPed	0.3	MG
1	45	HALOPERIDOL LACTATE	Typical	IVPed	0.3	MG
1	1	HALOPERIDOL LACTATE	Typical	IVPed	0.35	MG
1	3	HALOPERIDOL LACTATE	Typical	IVPed	0.35	MG
1	4	HALOPERIDOL LACTATE	Typical	IVPed	0.4	MG
3	1	HALOPERIDOL LACTATE	Typical	IVPed	0.5	MG

**Table 3a. Counts for Value-Combinations of Generic Drug Name, Route of Administration, Dose Strength, Unit of Measurement, and Type of Antipsychotic Administered During Inpatient Stay Among Infants <180 Days and Length of Stay >3 Days**

<b>Number of Inpatient Encounters Among Infants &lt;180 Days and Length of Stay &gt;3 Days</b>	<b>Frequency of Antipsychotic Administrations</b>	<b>Generic Drug Name</b>	<b>Type of Antipsychotic Medication (Typical, Atypical)</b>	<b>Route of Administration<sup>1</sup></b>	<b>Dose Strength</b>	<b>Unit of Measurement</b>
1	5	HALOPERIDOL LACTATE	Typical	IVPed	0.5	MG
1	7	HALOPERIDOL LACTATE	Typical	IVPed	0.5	MG
1	4	HALOPERIDOL LACTATE	Typical	IVPed	0.6	MG
1	1	HALOPERIDOL LACTATE	Typical	IVPed	0.7	MG
1	2	HALOPERIDOL LACTATE	Typical	IVPed	0.7	MG
1	1	OLANZAPINE	Atypical	IM	5	MG
1	18	OLANZAPINE	Atypical	PO	1.25	MG
1	53	OLANZAPINE	Atypical	PO	2.5	MG
1	2	OLANZAPINE	Atypical	PO	5	MG

<sup>1</sup>Values populated by Hospital Corporation of America (HCA) in the Sentinel Common Data Model (SCDM) inpatient pharmacy table.

**Table 3b. Counts for Value-Combinations of Generic Drug Name, Route of Administration, Dose Strength, Unit of Measurement, and Type of Antipsychotic Administered During Inpatient Stay Among Infants <180 Days**

Number of Inpatient Encounters Among Infants <180 Days	Frequency of Antipsychotic Administrations	Generic Drug Name	Type of Antipsychotic Medication (Typical, Atypical)	Route of Administration <sup>1</sup>	Dose Strength	Unit of Measurement
1	10	CHLORPROMAZINE HCL	Typical	PER TUBE	7	MG
1	3	CHLORPROMAZINE HCL	Typical	PO	5	MG
1	11	CHLORPROMAZINE HCL	Typical	PO	6.25	MG
1	147	CHLORPROMAZINE HCL	Typical	PO	10	MG
1	19	HALOPERIDOL	Typical	FEED-TUBE	0.1	MG
1	1	HALOPERIDOL	Typical	FEED-TUBE	0.15	MG
1	13	HALOPERIDOL	Typical	FEED-TUBE	0.2	MG
1	4	HALOPERIDOL	Typical	FEED-TUBE	0.3	MG
1	5	HALOPERIDOL	Typical	FEED-TUBE	0.3	MG
1	9	HALOPERIDOL	Typical	FEED-TUBE	0.3	MG
1	43	HALOPERIDOL	Typical	FEED-TUBE	0.3	MG
1	9	HALOPERIDOL	Typical	FEED-TUBE	0.4	MG
1	11	HALOPERIDOL	Typical	FEED-TUBE	0.5	MG
1	27	HALOPERIDOL	Typical	FEED-TUBE	0.5	MG
1	1	HALOPERIDOL	Typical	FEED-TUBE	0.6	MG
1	22	HALOPERIDOL	Typical	FEED-TUBE	0.6	MG
1	2	HALOPERIDOL	Typical	IV	4	MG
1	28	HALOPERIDOL	Typical	PO	0.1	MG
1	1	HALOPERIDOL	Typical	PO	0.3	MG
1	3	HALOPERIDOL	Typical	PO	0.45	MG
1	1	HALOPERIDOL	Typical	TU	0.25	MG
1	9	HALOPERIDOL	Typical	TU	0.5	MG
1	1	HALOPERIDOL LACTATE	Typical	.ROUTE	0.1	MG
1	1	HALOPERIDOL LACTATE	Typical	.ROUTE	0.15	MG
1	6	HALOPERIDOL LACTATE	Typical	IV	0.5	MG
1	11	HALOPERIDOL LACTATE	Typical	IVPed	0.1	MG
1	2	HALOPERIDOL LACTATE	Typical	IVPed	0.15	MG
2	1	HALOPERIDOL LACTATE	Typical	IVPed	0.2	MG
1	8	HALOPERIDOL LACTATE	Typical	IVPed	0.2	MG
1	10	HALOPERIDOL LACTATE	Typical	IVPed	0.2	MG
1	19	HALOPERIDOL LACTATE	Typical	IVPed	0.25	MG
1	1	HALOPERIDOL LACTATE	Typical	IVPed	0.27	MG
1	1	HALOPERIDOL LACTATE	Typical	IVPed	0.3	MG
3	2	HALOPERIDOL LACTATE	Typical	IVPed	0.3	MG
1	8	HALOPERIDOL LACTATE	Typical	IVPed	0.3	MG
1	45	HALOPERIDOL LACTATE	Typical	IVPed	0.3	MG
1	1	HALOPERIDOL LACTATE	Typical	IVPed	0.35	MG
1	3	HALOPERIDOL LACTATE	Typical	IVPed	0.35	MG
1	4	HALOPERIDOL LACTATE	Typical	IVPed	0.4	MG
3	1	HALOPERIDOL LACTATE	Typical	IVPed	0.5	MG
1	5	HALOPERIDOL LACTATE	Typical	IVPed	0.5	MG

**Table 3b. Counts for Value-Combinations of Generic Drug Name, Route of Administration, Dose Strength, Unit of Measurement, and Type of Antipsychotic Administered During Inpatient Stay Among Infants <180 Days**

<b>Number of Inpatient Encounters Among Infants &lt;180 Days</b>	<b>Frequency of Antipsychotic Administrations</b>	<b>Generic Drug Name</b>	<b>Type of Antipsychotic Medication (Typical, Atypical)</b>	<b>Route of Administration<sup>1</sup></b>	<b>Dose Strength</b>	<b>Unit of Measurement</b>
1	7	HALOPERIDOL LACTATE	Typical	IVPed	0.5	MG
1	4	HALOPERIDOL LACTATE	Typical	IVPed	0.6	MG
1	1	HALOPERIDOL LACTATE	Typical	IVPed	0.7	MG
1	2	HALOPERIDOL LACTATE	Typical	IVPed	0.7	MG
1	1	OLANZAPINE	Atypical	IM	5	MG
1	18	OLANZAPINE	Atypical	PO	1.25	MG
1	53	OLANZAPINE	Atypical	PO	2.5	MG
1	2	OLANZAPINE	Atypical	PO	5	MG

<sup>1</sup>Values populated by Hospital Corporation of America (HCA) in the Sentinel Common Data Model (SCDM) inpatient pharmacy table.

**Table 4. Proportion of Hospital Corporation of America (HCA) Facilities with Neonatal Intensive Care Units (NICU) in All Inpatient Encounters Among Infants <180 Days and Length of Stay >3 Days between July 1, 2011 and September 30, 2017**

Description	Total Number	Percent of Total HCA Facilities
HCA Facilities <sup>1</sup>	120	100%
Any NICU	88	73%
Level III NICU <sup>2</sup>	53	44%
Level IV NICU <sup>3</sup>	5	4%

<sup>1</sup>Facilities from which inpatient encounters in infants <180 days and length of stay >3 days were identified between July 1, 2011 and September 30, 2017.

<sup>2</sup>Level III NICUs provide care for babies born at less than 32 weeks gestation as well as babies with critical illness at all gestational ages. These facilities provide prompt and readily available access to a full range of pediatric medical subspecialists. They also provide sustained life support, offer a full range of respiratory support, and perform advanced imaging.

<sup>3</sup>Level IV NICUs (regional NICUs) provide the highest level and most acute care. These facilities are required to have pediatric surgical subspecialties within institutions capable of providing surgical repair of complex congenital or acquired conditions. They maintain a full range of pediatric medical subspecialists, pediatric surgical subspecialists, and pediatric anesthesiologists on site.

\*\* Among the 4 facilities that had inpatient encounters in infants with any antipsychotic use: 2 of the facilities were Level III NICU and 2 were Level IV NICU.

**Appendix A. Start and End Dates for the Data Partner as of Request Distribution Date (August 15, 2019)**

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DP ID	DP Start Date*	DP End Date*
DP01	07/01/2011	09/30/2017

\*Start Date and End Date are first calculated by individual table (enrollment, dispensing, etc). End Date is defined as the greatest year-month with a record count that is within 80% of the previous year-month. After Start and End Dates are calculated by individual tables, the overall End Date is the minimum of all the table End Dates.

**Appendix B. Generic and Brand Drug Names Used to Define Atypical and Typical Antipsychotics in this Request**

Generic Drug Name	Brand Drug Name
<b>Atypical Antipsychotics</b>	
ARIPIRAZOLE	Abilify
ARIPIRAZOLE	Abilify Discmelt
ARIPIRAZOLE	aripiprazole
ASENAPINE MALEATE	Saphris
ASENAPINE MALEATE	Saphris (black cherry)
BREXPIRAZOLE	Rexulti
CARIPRAZINE HCL	Vraylar
CLOZAPINE	clozapine
CLOZAPINE	Clozaril
CLOZAPINE	FazaClo
CLOZAPINE	Versacloz
ILOPERIDONE	Fanapt
LURASIDONE HCL	Latuda
OLANZAPINE	olanzapine
OLANZAPINE	Zyprexa
OLANZAPINE	Zyprexa Zydis
OLANZAPINE/FLUOXETINE HCL	olanzapine-fluoxetine
OLANZAPINE/FLUOXETINE HCL	Symbyax
PALIPERIDONE	Invega
PALIPERIDONE	paliperidone
PIMAVANSERIN TARTRATE	Nuplazid
QUETIAPINE FUMARATE	quetiapine
QUETIAPINE FUMARATE	Seroquel
QUETIAPINE FUMARATE	Seroquel XR
RISPERIDONE	Risperdal
RISPERIDONE	Risperdal M-TAB
RISPERIDONE	risperidone
ZIPRASIDONE HCL	Geodon
ZIPRASIDONE HCL	ziprasidone HCl
ZIPRASIDONE MESYLATE	Geodon
<b>Typical Antipsychotics</b>	
CHLORPROMAZINE HCL	chlorpromazine
CHLORPROMAZINE HCL	Thorazine
FLUPHENAZINE ENANTHATE	Prolixin
FLUPHENAZINE HCL	fluphenazine HCl
FLUPHENAZINE HCL	Permitil
FLUPHENAZINE HCL	Prolixin
HALOPERIDOL	haloperidol
HALOPERIDOL LACTATE	Haldol
HALOPERIDOL LACTATE	haloperidol lactate
LOXAPINE	Adasuve
LOXAPINE HCL	Loxitane
LOXAPINE HCL	Loxitane-C
LOXAPINE SUCCINATE	loxapine succinate
LOXAPINE SUCCINATE	loxapine succinate (bulk)

**Appendix B. Generic and Brand Drug Names Used to Define Atypical and Typical Antipsychotics in this Request**

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<b>Generic Drug Name</b>	<b>Brand Drug Name</b>
LOXAPINE SUCCINATE	Loxitane
MESORIDAZINE BESYLATE	Serentil
MOLINDONE HCL	Moban
MOLINDONE HCL	molindone
PERPHENAZINE	perphenazine
PERPHENAZINE	perphenazine (bulk)
PERPHENAZINE	Trilafon
PERPHENAZINE/AMITRIPTYLINE HCL	perphenazine-amitriptyline
PIMOZIDE	Orap
PIMOZIDE	pimozide
PROCHLORPERAZINE MALEATE	Compazine
PROCHLORPERAZINE MALEATE	prochlorperazine maleate
THIORIDAZINE HCL	Mellaril
THIORIDAZINE HCL	Mellaril-S
THIORIDAZINE HCL	thioridazine
THIORIDAZINE HCL	thioridazine (bulk)
THIOTHIXENE	Navane
THIOTHIXENE	thiothixene
THIOTHIXENE HCL	Navane
THIOTHIXENE HCL	thiothixene HCl
TRIFLUOPERAZINE HCL	Stelazine
TRIFLUOPERAZINE HCL	trifluoperazine
TRIFLUPROMAZINE HCL	Vesprin