

Pediatric Utilization Patterns of Opioid Analgesics (OAs)

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September 26, 2019

Meeting of the Pediatric Advisory Committee

Outline

- National sales distribution data
- Outpatient retail pharmacy utilization data
 - Prescription and patient level data
 - Top prescriber specialties
- Office-based physician surveys
 - Top diagnoses
- Limitations
- Summary

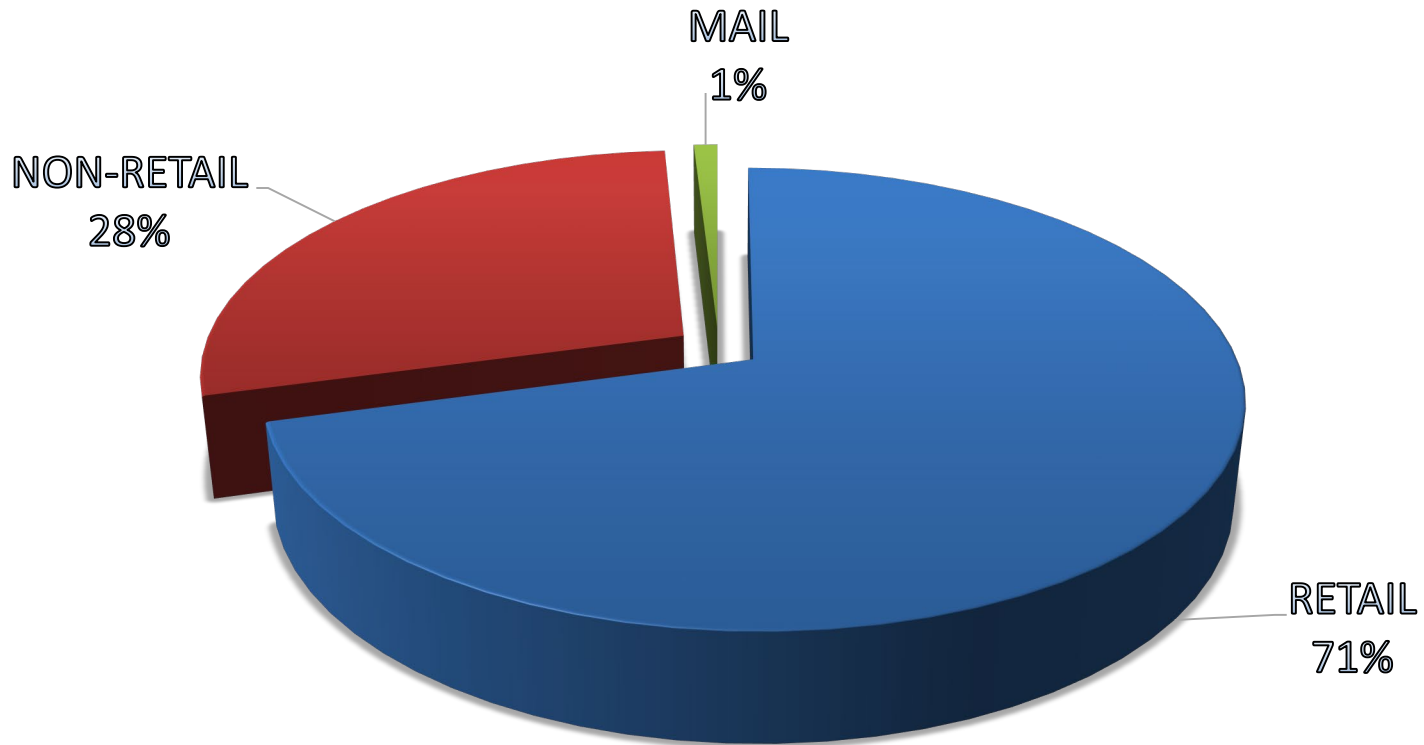
Selected Opioid Analgesics (OAs)



Extended-Release/Long-Acting Formulation (ER/LA)	Immediate-Release Formulation (IR)
<ul style="list-style-type: none"> • Buprenorphine Transdermal • Buprenorphine • Fentanyl Transdermal • Hydrocodone • Hydromorphone • Methadone • Morphine • Morphine-Naltrexone • Oxycodone • Oxycodone-Acetaminophen • Oxymorphone • Tapentadol • Tramadol 	<ul style="list-style-type: none"> • Butalbital • Butorphanol • Codeine • Codeine-Acetaminophen • Dihydrocodeine-aspirin-caffeine • Dihydrocodeine-acetaminophen-caffeine • Hydrocodone-Acetaminophen • Hydrocodone-Aspirin • Hydrocodone-Ibuprofen • Hydromorphone • Levorphanol • Meperidine • Meperidine-Promethazine • Morphine • Opium • Oxycodone • Oxycodone-Acetaminophen • Oxycodone-Aspirin • Oxycodone-Ibuprofen • Oxymorphone • Pentazocine-Acetaminophen • Pentazocine-Naloxone • Propoxyphene • Propoxyphene-Acetaminophen • Tapentadol • Tramadol • Tramadol-Acetaminophen • Transmucosal Immediate-Release Fentanyl (TIRF)

Does not include injectable formulations of opioid analgesics, opioid-containing Medication-Assisted Therapy (MAT) products and opioid-containing cough/cold products

U.S. Sales Distribution for Opioid Analgesics 2018



■ RETAIL ■ NON-RETAIL ■ MAIL

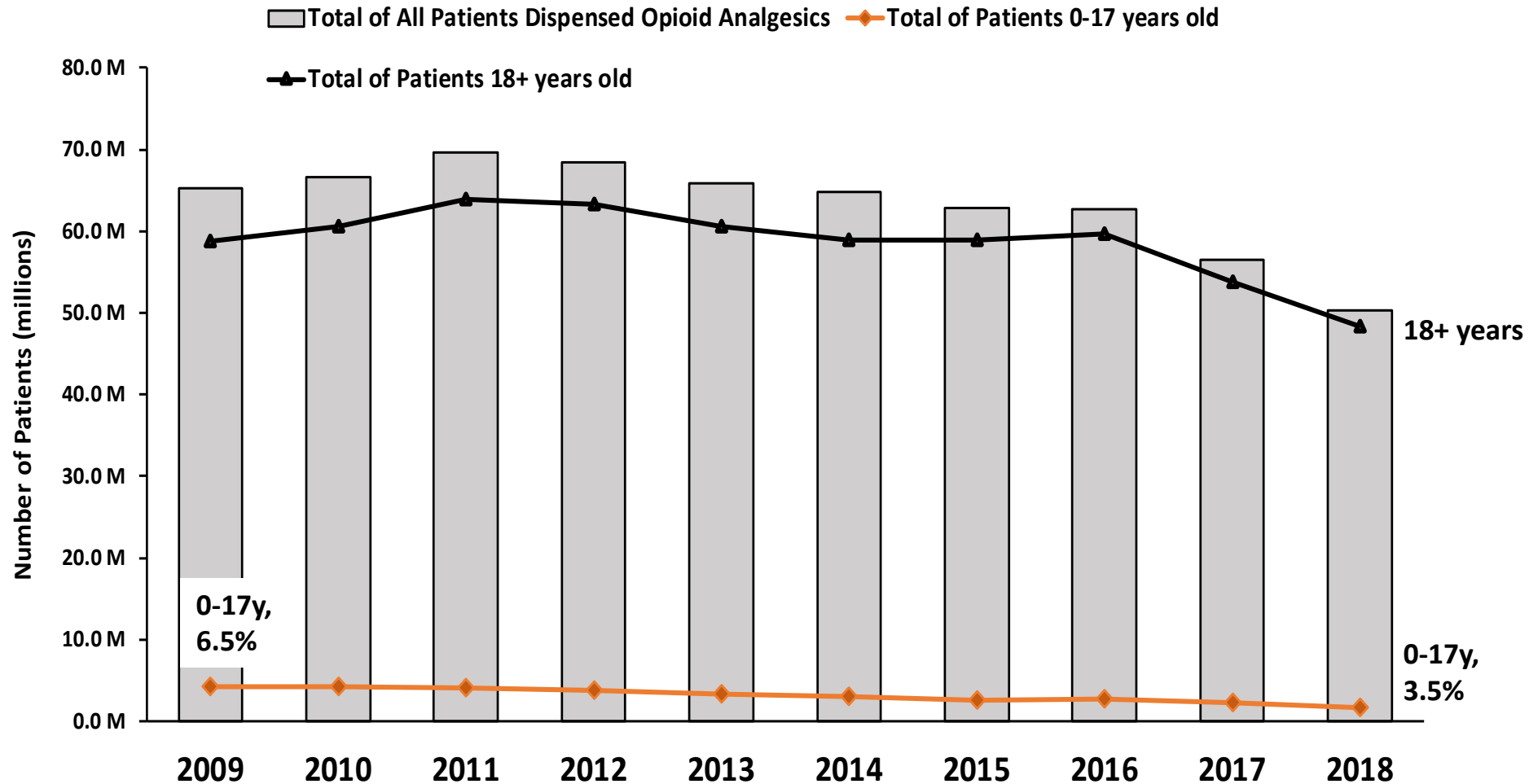
Data Source: IQVIA National Sales Perspective, 2019. Data extracted July 2019

Prescription Utilization Databases



- **IQVIA National Prescription Audit™ (NPA)**
 - Measures prescriptions dispensed from outpatient retail pharmacies to patients
 - Data are projected to provide national estimates of utilization
- **IQVIA Total Patient Tracker™ (TPT)**
 - Measures the total number of unique patients in the retail pharmacies
 - Data are projected to provide national estimates

Opioid Analgesic Utilization

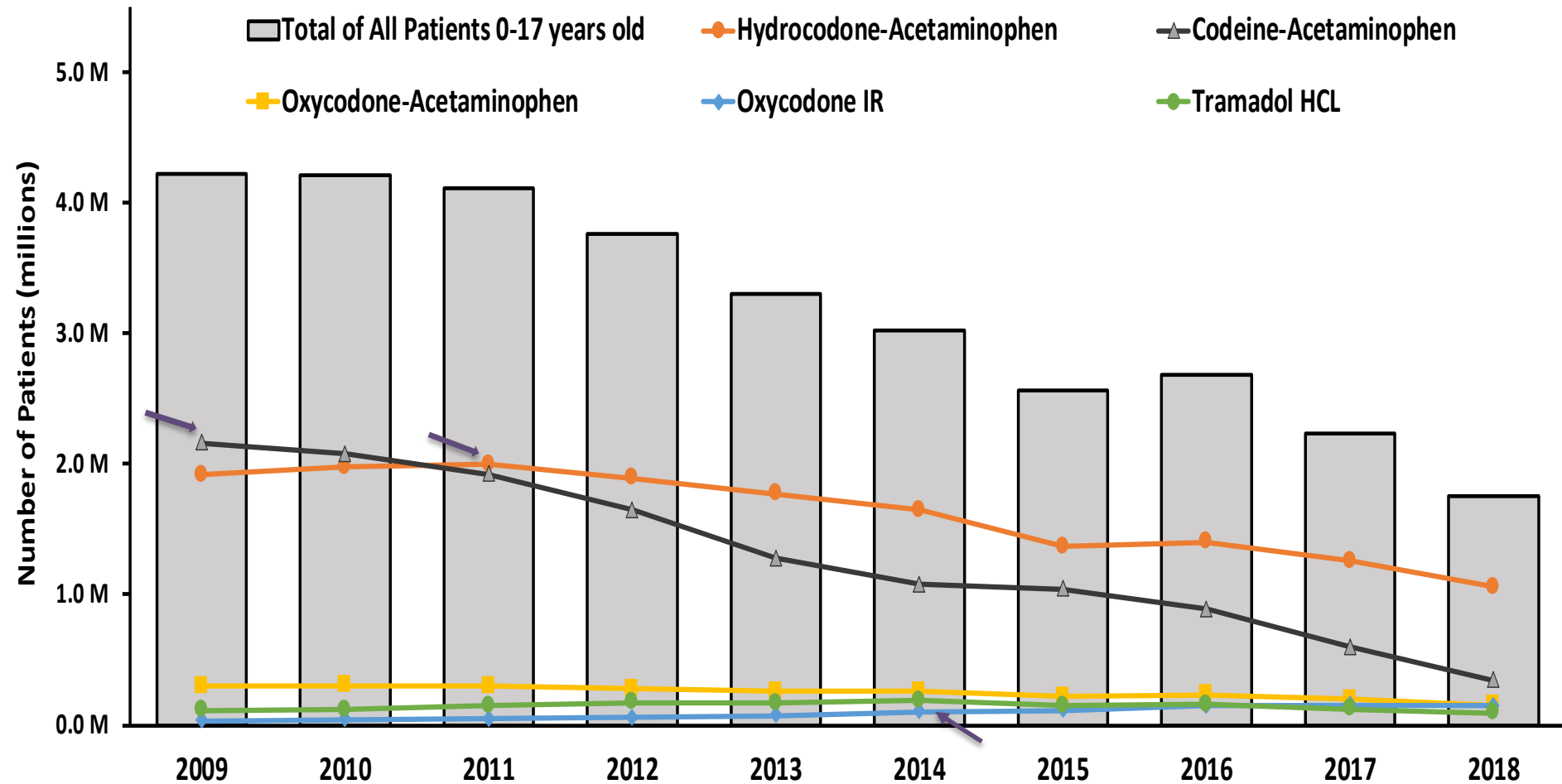


National estimates of all patients who received prescriptions dispensed for opioid analgesics from U.S. outpatient retail pharmacies*, 2009-2018

Data Source: IQVIA Total Patient Tracker™. 2009-2018. Data extracted July, 2019.

*Of note, there was a change in the underlying data and methodology of the proprietary database, IQVIA NPA, to manage prescription claims that are voided and/or reversed. Because TPT patient data are derived from NPA prescription data, projected patient estimates have been adjusted and restated in the database back to January 2017, data prior to 2017 remain unadjusted. As a result, a trend break occurs between the 2016 and 2017 patient estimates who received prescriptions dispensed from retail pharmacies.

Pediatric Patients: Opioid Analgesic

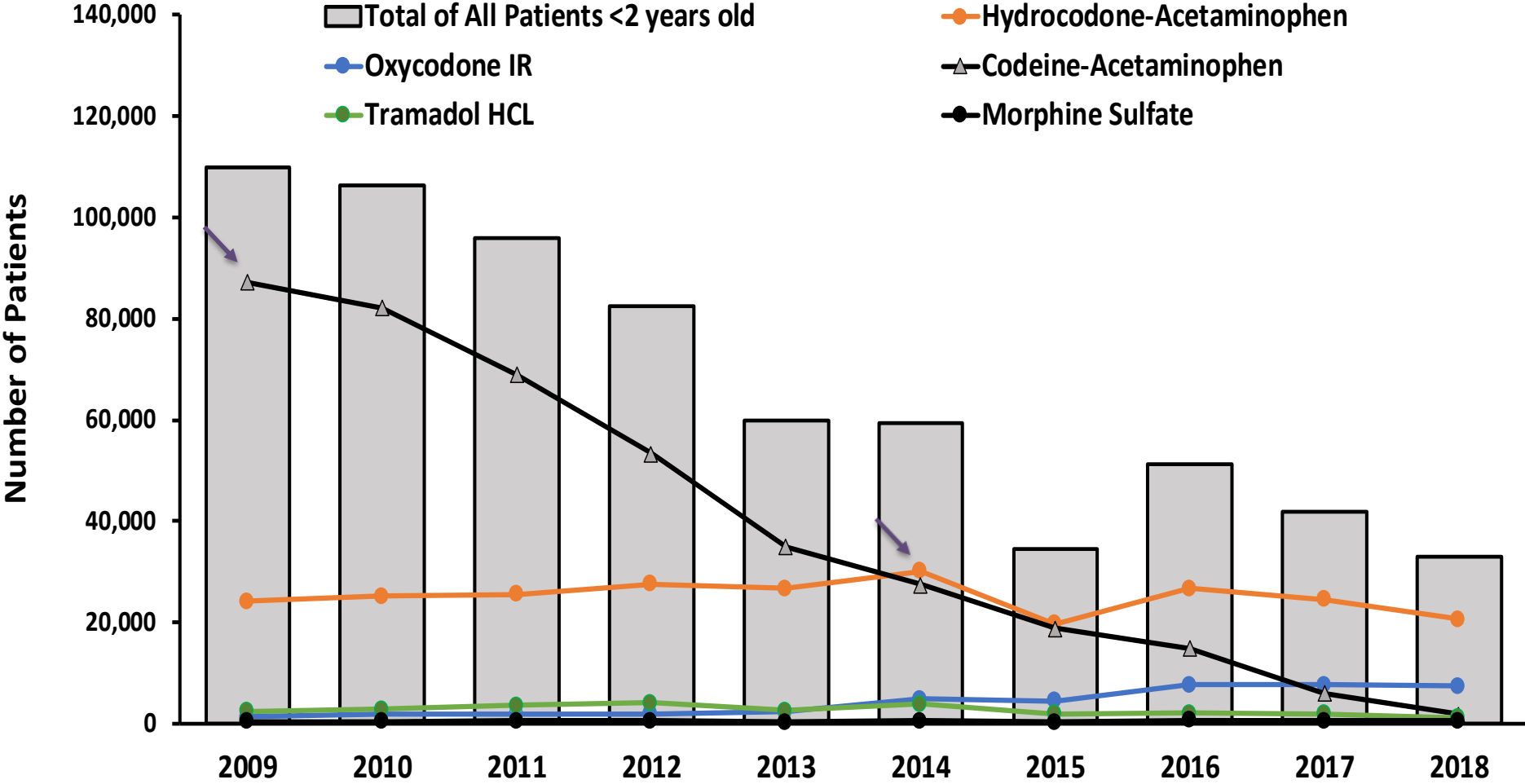


Estimated number of pediatric patients* (0-17 years old) who received prescriptions dispensed for all OAs (grey bar) and for the top 5 OAs (solid lines), from U.S. outpatient retail pharmacies, 2009-2018

Data Source: IQVIA Total Patient Tracker™. 2009-2018. File: TPT USC 022 by Age_2009-2018_7_18_19.xlsx. Data extracted July 2019.

Of note, there are changes in the underlying data and methodology of the proprietary database IQVIA NPA to account for a dynamic pharmaceutical market, including a change to manage prescription claims that are voided or reversed, prescription volumes dispensed from the retail pharmacies have been historically adjusted back to January 2017, data prior to January 2017 have not been adjusted to the new methodology. In 2018, an estimated 2% of total prescription claims for opioid analgesics dispensed from U.S. retail pharmacies appears to have been voided or reversed.*Note: Patient age groups are inclusive of all patients up to the day before their next birthday. For example, patients age 0-17 years include patients less than 18 years of age (17 years and 11 months).

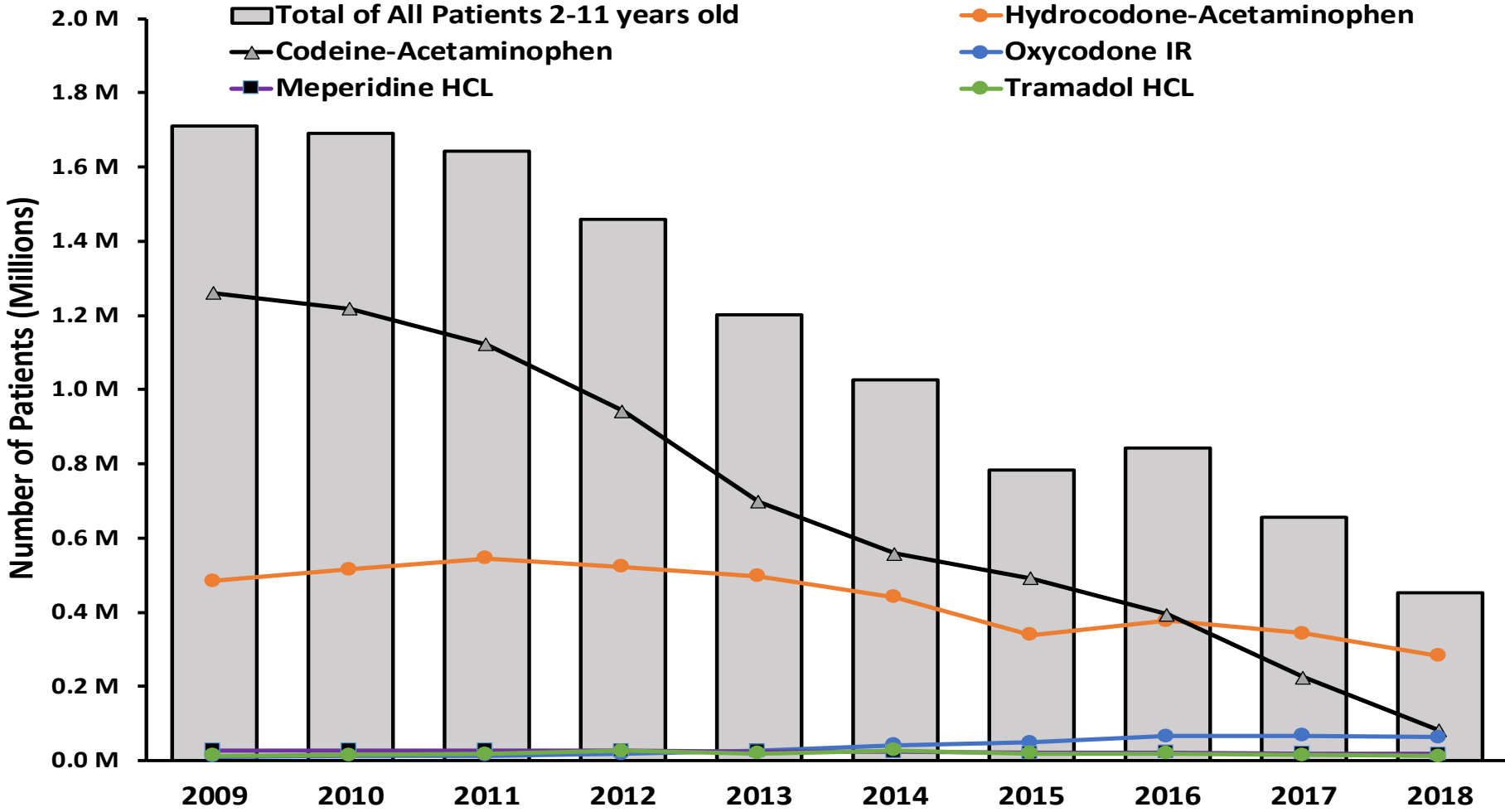
Opioid Analgesic Utilization (<2 Years Old)



Estimated number of pediatric patients* (< 2 years old) who received prescriptions dispensed for all OAs (grey bar) and for the top 5 OAs (solid lines), from U.S. outpatient retail pharmacies, 2009-2018

Data Source: IQVIA Total Patient Tracker™. 2009-2018. Data extracted July 2019.
 Of note, there are changes in the underlying data and methodology of the proprietary database IQVIA NPA to account for a dynamic pharmaceutical market, including a change to manage prescription claims that are voided or reversed, prescription volumes dispensed from the retail pharmacies have been historically adjusted back to January 2017, data prior to January 2017 have not been adjusted to the new methodology. In 2018, an estimated 2% of total prescription claims for opioid analgesics dispensed from U.S. retail pharmacies appears to have been voided or reversed.
 *Note: Patient age groups are inclusive of all patients up to the day before their next birthday.

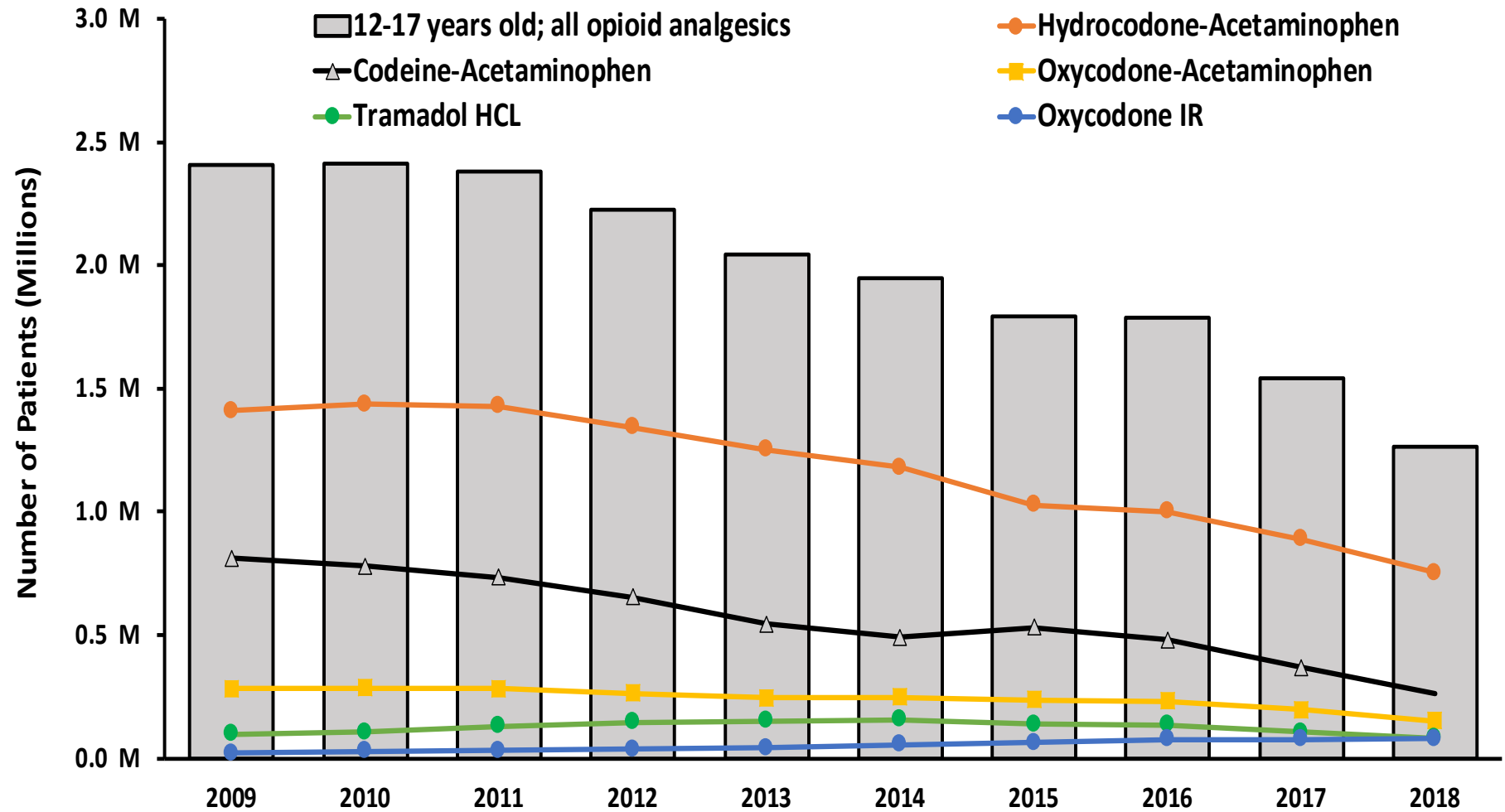
Opioid Analgesic Utilization (2-11 Years Old)



Estimated number of pediatric patients* (2-11 years old) who received prescriptions dispensed for all OAs (grey bar) and for the top 5 OAs (solid lines), from U.S. outpatient retail pharmacies, 2009-2018

Data Source: IQVIA Total Patient Tracker™. 2009-2018. Data extracted July 2019.
 Of note, there are changes in the underlying data and methodology of the proprietary database IQVIA NPA to account for a dynamic pharmaceutical market, including a change to manage prescription claims that are voided or reversed, prescription volumes dispensed from the retail pharmacies have been historically adjusted back to January 2017, data prior to January 2017 have not been adjusted to the new methodology. In 2018, an estimated 2% of total prescription claims for opioid analgesics dispensed from U.S. retail pharmacies appears to have been voided or reversed.
 *Note: Patient age groups are inclusive of all patients up to the day before their next birthday.

Opioid Analgesic Utilization (12-17 Years Old)



Estimated number of pediatric patients* (12-17 years old) who received prescriptions dispensed for all OAs (grey bar) and for the top 5 OAs (solid lines), from U.S. outpatient retail pharmacies, 2009-2018

Data Source: IQVIA Total Patient Tracker™. 2009-2018. Data extracted July 2019.
 Of note, there are changes in the underlying data and methodology of the proprietary database IQVIA NPA to account for a dynamic pharmaceutical market, including a change to manage prescription claims that are voided or reversed, prescription volumes dispensed from the retail pharmacies have been historically adjusted back to January 2017, data prior to January 2017 have not been adjusted to the new methodology. In 2018, an estimated 2% of total prescription claims for opioid analgesics dispensed from U.S. retail pharmacies appears to have been voided or reversed.
 *Note: Patient age groups are inclusive of all patients up to the day before their next birthday.

Prescription Data:

Top Prescribing Specialties 2018



- Pediatric patients **0-17 years** old received **1.2%** of total **168 million** OA prescriptions
- **<2 years old (2%** of prescriptions dispensed to 0-17 year old)
 - Urology (31%)
 - Surgical Specialties* (15%)
 - Nurse Practitioners and Physician Assistants (11%)
- **2 - 11 years old (25%** of prescriptions dispensed to 0-17 year old)
 - Otolaryngology (26%)
 - Surgical Specialties* (18%)
 - Dentistry (12%)
- **12 - 17 years old (73%** of prescriptions dispensed to 0-17 year old)
 - Surgical Specialties* (46%)
 - Dentistry (16%)
 - Nurse Practitioners and Physician Assistants (10%)

Source: IQVIA National Prescription Audit™. 2019. Data extracted June 2019.

*Surgical Specialties include cardiothoracic surgery, general surgery, neurological surgery, orthopedic surgery of the spine, orthopedic surgery, pediatric neuro surgery, plastic surgery, thoracic surgery, critical care surgery, colon and rectal surgery, cardiovascular surgery and other surgical specialties.

U.S. Office-Based Physician Survey Data



- Syneos Health Research & Insights LLC., TreatmentAnswers™ with Pain Panel
- Monthly survey of 3,200 **office-based physicians** representing 30 specialties with 115 pain specialists
- Data are projected to reflect national prescribing patterns
- Data provide insight into prescriber intent
- Dentists are not included

Diagnosis Data for Opioid Analgesics for Pediatric Patients in 2018



- **Patient Ages: <2 years old**
 - Fractures and Injuries (63%)
 - Other and unspecified soft tissue disorders, not elsewhere classified (38%)
- **Patient Ages: 2 - 11 years old**
 - Fractures and Injuries (76%)
 - Inguinal hernia (13%)
- **Patient Ages: 12 - 17 years old**
 - Fractures and Injuries (32%)
 - Scoliosis (8%)

***Dentists** are not included in this Database

Source: Syneos Health Research & Insights LLC., TreatmentAnswers™. 2018. Data extracted July 2019.

*Diagnosis data are not directly linked to dispensed prescriptions but are obtained from surveys of a sample of 3,200 office-based physicians reporting on patient activity during one day per month. Patient age groups are inclusive of all patients up to the day before their next birthday. For example, patients aged <18 years include patients less than 18 years old (17 years and 11 months).

Limitations

- Only dispensing patterns in the outpatient retail setting was assessed
- Diagnoses data are not necessarily linked to dispensed prescriptions
- Diagnoses data were derived from surveys of office-based practices (does not include dental practices)

Summary

- In 2018, 1.8 million pediatric patients received OA prescriptions (59% decrease from 2009) in the outpatient retail setting
- Top 5 OAs among pediatric patients in 2018:
 - Hydrocodone-acetaminophen, codeine-acetaminophen, oxycodone-acetaminophen, single-ingredient oxycodone IR and single-ingredient tramadol
- Decrease in use was primarily driven by decreases in codeine/acetaminophen and hydrocodone/acetaminophen

Summary (continued)



- Single-ingredient oxycodone IR increased in use from 2009-2018 but remained relatively low
- OAs were most frequently prescribed to pediatric patients by surgical specialists, primary care, and dentists
- Surveys of office-based physicians show OAs were mainly used for management of acute conditions (fractures, injuries and inguinal hernia) in pediatric patients

Thank You

